MATER PRIVATE HOSPITAL – PATHOLOGY LABORATORY	
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Document format amended in line with Hospital Policy POL-GEN-0021 Changes as per change requests on Q-Pulse	
Reason for Change	
Updated Procedure: Change requests as detailed in document record	

USER HANDBOOK

Please see electronic signatures

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1. Quality Policy of the Pathology Laboratory, Mater Private Hospital, Dublin

The Pathology Laboratory provides a histopathology, non-gynae cytology, microbiology, immunology, biochemistry/endocrinology, haematology and blood transfusion service and is committed to promoting and providing the highest quality diagnostic and consultative services for all its users.

In order to ensure that the needs and requirements of users are met, the Pathology Laboratory will:-

- Operate a quality management system to integrate the organisation, procedures, processes and resources to ensure the best possible care for the patient.
- Establish & review quality objectives and plans in order to implement this quality policy.
- Ensure that all personnel are familiar with this quality policy and adhere to Hospital policies and procedures to ensure user satisfaction, quality and safety
- Commit to the health, safety and welfare of its entire staff. Visitors to the department will be treated with respect and due consideration will be given to their safety while on site.
- Uphold professional values and continue to be committed to good professional practice and ethical conduct and patient confidentiality.

The Pathology Laboratory will comply with the International Standard ISO 15189, EU Directive 2002/98/EC, "Minimum Requirements for Blood Bank Compliance with Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of EU Directive 2002/98/EC" (AML-BB), S.I. No 547 of 2006 and S.I. No 360 of 2005, INAB Terms & Conditions, Regulations and Policy Documents & current environmental legislation, for the services and tests defined in the Quality Manual and scope http://www.inab.ie/Directory-of-Accredited-Bodies/Laboratory -Accreditation/Medical-Testing/The-Mater-Private-Hospital.html of accreditation and is committed to:-

- Staff recruitment, training, development and retention at all levels to provide a full and effective service to its users.
- The proper procurement and maintenance of such equipment and other resources as are needed for the provision of the service.
- The collection, transport and handling of all specimens in such a way as to ensure the correct performance of laboratory examinations.
- The use of examination procedures that will ensure the highest achievable quality of all tests performed.
- Reporting results of examinations in ways which are timely, confidential, accurate and clinically useful and advocate patient safety at all times.
- The assessment of user satisfaction, in addition to internal audit and external quality assessment, in order to produce continual quality improvement.
- Monitoring and review of the service through quality indicators, quality objectives and improvements in order to enhance the service provided to the patient.
- The safe testing, distribution and transfusion of blood and blood products, including 100% traceability of blood components.
- The investigation and reporting of serious adverse events and reactions and reporting to the relevant authority, where applicable, in a timely manner.
- In the unlikely event of Laboratory closure, acquisition or merger, the current Laboratory Management will endeavour to ensure the ongoing integrity of patients and availability of patients' records.

Approved by:  Date: 15/09/2025

Dr Niall Mulligan, Laboratory Director

Approved by:  Date: 15/09/2025

Mr Paul Kennedy Laboratory Manager

2. MANAGEMENT AND RELEASE OF INFORMATION

2.1 Management of information

We value your privacy and well-being while you are a patient and service user of Laboratory Services of the Mater Private Hospital Dublin. The following information is in relation to your admission and the processing of your personal data.

You will be asked for your written, informed consent for specific procedures. Full list available. Your personal information will be required for the provision and administration of laboratory services. As our patient, you consent that medical data which relates to your medical history, can be accessed by other medical facilities to ensure they have sufficient information for the continuous delivery of safe care to you.

You understand that your medical data may be shared with other hospitals and treating Consultants involved in your care pathway as part of your admission to Mater Private.

Your clinical records including your medical chart may be used for clinical audit.

Please be assured that any processing of your personal data will be done in compliance with the General Data Protection Regulation, the Irish Data Protection Act (2018) and related legislation.

Following your treatment, the Hospital may contact you, solely for the purpose of seeking your feedback and comments in relation to the care you have received including laboratory services.

It is the policy of the laboratory that it shall inform the user and/or the patient in advance, of the information it intends to place in the public domain. Except for information that the user and/or the patient makes publicly available, or when agreed between the laboratory and the patient (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

2.2 Release of information

When the laboratory is required by law or authorised by contractual arrangements to release confidential information, the patient concerned shall be notified of the information

released, unless prohibited by law. . In Ireland, notifiable disease reporting is mandatory and does not require patient consent, but where possible patients should be informed. The laboratory will ensure full confidentiality is maintained and that only the minimum required data is shared.

Information about the patient from a source other than the patient (e.g. complainant, regulator) shall be kept confidential by the laboratory. The identity of the source shall be kept confidential by the laboratory and shall not be shared with the patient, unless agreed by the source.

Sharing information with third parties outside of the Mater Private Network, i.e. public or voluntary hospitals, referral laboratory specialists etc. is done on a need-to-know basis if there is a genuine need in order to ensure the highest quality of care is provided. Only information that is necessary for this purpose is shared.

In compliance with the Patient Safety (Notifiable Incidents and Open Disclosures) Act 2023 and in keeping with the Mater Private's commitment to our patients, it is the policy of the Mater Private that patients/relevant person are communicated with in an open, honest, transparent and empathetic manner following patient safety incidents and that they are provided with a sincere and meaningful apology in a timely manner in accordance with the 10 Principles of Open Disclosure (See POL-GEN-113).

3. PATIENT INFORMATION REQUESTS

The Hospital Quality Department manage patient, General Data Protection (GDPR) Subject Access Requests (SAR) and Solicitor requests. The request can either be a test(s) results &/or medical record(s).

3.1 Patient Requests

The Quality Department require the following information in order to process your request:

- The request must be sent via email to Quality.admin@materprivate.ie or in writing to Mater Private Network Dublin, Quality Department, Eccles St, Dublin 7, D07 WKW8

- Full name, Date of Birth & current address, patient number
- Photographic Identification (passport/driving license/public services card) to ensure correct identification.

Under General Data Protection Regulation (GDPR):

- The turnaround time for a request is 30 days
- Please be advised all third-party information is redacted
- Chart requests are posted out via registered mail

Under the Data Protection (Access Modification) (Health) Regulations, 1989:
A medical professional must either discuss the results of a test with the patient or approve the release of the test results to the patient, if a recent test has not been discussed with the patient initially by their consultant or General Practitioner (GP), the Quality Department are required to notify the admitting or referring clinician of the request. The Act prohibits a person who is not a health professional from disclosing health data to an individual without first consulting the individual's doctor, or some other suitably qualified health professional.

Inpatient requests can only commence once you have been discharged from hospital.

Urgent requests, other hospitals &/or Healthcare Practitioners can request the records directly from the Medical Records Department medicalrecords@materprivate.ie. Written consent will be required from the patient.

3.2 Other Requests:

3.2.1 Deceased Patient / Next of Kin Requests

Please provide the following:

- proof of identity of the Next of Kin
- signed Solicitor Authority
- copy of the deceased patient's Death Certificate

- Executor Request:
- Death Cert
- Proof of Executor(s): e.g., Grant of Probate/ Letter of Probate
- ID for each executor

3.2.2 Requests on behalf of a patient by a family member:

Written consent must be obtained from the patient, where they have the capacity to do so. The request can be processed on provision of all the request requirements listed above in point no. 1 and proof of Next of Kin identification.

Ref.: PIL-QTY-001 Medical Test/Record Requests - Patient Information Leaflet
MPN-FRM-GEN-GRP-001 General Consent terms for admission & treatment

4. REQUIREMENTS REGARDING PATIENTS

Establishing and implementing a process that ensures our patient's well-being, safety, and rights in the laboratory at the Mater Private Network, Dublin, requires a structured and proactive approach. By developing clear policies, training staff, enhancing communication, and continuously improving through feedback and monitoring, the laboratory can provide high-quality care while prioritising patient-centred outcomes. This ensures not only compliance with regulations but also the trust and confidence of our patients in the care they receive. Below are key steps that are implemented across the hospital and are mirrored in the laboratory processes.

4.1 Develop a Patient-Centred Policy Framework

- **Patient Safety Protocol:** Mater Private Network (MPN) as the premium private operator for high acuity tertiary care in Ireland, is built upon high-quality and highly complex care, underpinned by strong clinical performance, and assessed against leading international benchmarks. MPN is committed to building our reputation as the

best place to receive care, to work and to practice medicine. On an annual basis, the Quality and Patient Safety Plan is integrated with the strategic service plan as well as being a standalone plan.

Ref.: PLA-QUA-001 Mater Private Group Quality and Patient Safety Plan 2024 Patient

- **Rights Charter**: The Patient Charter is one of the information leaflets given to patients of the Mater Private Network Dublin. This Patient Charter outlines what our patients should expect with regards to their medical care and treatment (which includes laboratory services), consent, privacy and confidentiality, safety and security and the hospital's complaints procedure.
- **Compliance with Regulations**: The laboratory adheres to all national and international regulations related to patient safety and ethical conduct (e.g., ISO 15189 standards, GDPR for patient data protection).
- **Due Care & Respect** – Through stakeholder engagement, ethical and legal considerations, transparency, accountability and continuous improvement, the laboratory ensures that our patient's are the centre of our policies and procedures.

4.2 Ensure Comprehensive Staff Training

- All staff members are equipped with the necessary knowledge and skills to prioritise patient well-being, safety, and rights. Laboratory staff are regularly evaluated and competency assessed in performing tasks related to patient safety (e.g., correct test handling, emergency procedures).
- Staff in the laboratory have acknowledged and adhere to the Mater Private Network's Ethical Framework Procedure as outlined in POL-GEN-069.
- Regular training is provided on topics like patient confidentiality, proper handling of samples, and biohazard safety protocols.

4.3 Establish a Risk Management and Quality Assurance System

The laboratory management are committed to identifying, assessing, and mitigating risks to patient safety and well-being, while ensuring high-quality test results. This is achieved

through Risk Assessments, Incident Reporting, Internal Auditing and a robust internal and external Quality Control Programme.

4.4 Enhance Communication and Patient Engagement

The Mater Private Network including Laboratory Management ensures clear communication with patients regarding their laboratory tests, fostering trust and understanding. This is achieved through;

- **Transparency in Reporting**: Laboratory Management ensure that test results are communicated to patients promptly; with a clear explanation of findings where appropriate, ensuring they understand their implications. (See individual department sections below).
- **Feedback Mechanisms**: The laboratory is committed to supporting patients and laboratory users to provide helpful information to aid the laboratory in the selection of the examination methods, and the interpretation of the examination results. This is achieved through the use of a Patient Feedback forum on the Mater Private Network website patient feedback section or by emailing Laboratory.Feedback@materprivate.ie.

Please see section 4.14 of this User Handbook for more information.
Suggestions for improvements to the Laboratory service can be emailed directly to the Laboratory manager; Paul.Kennedy@materprivate.ie. Suggestions in relation to examination methods and interpretation of results will be directed to Consultant Head of Departments listed in Table 1 in section 5.3. Patients and users wishing to make a complaint about the Laboratory service should email the Laboratory Manager/Laboratory Quality Manager directly, Paul.Kennedy@materprivate.ie or Fiona.OBrien@materprivate.ie.
If it is not possible to solve the problem at department level, patients and users can also access the "How to make a formal complaint form" on the MPN website as shown above.

4.5 Implement Data Protection and Confidentiality Measures

Protection of patient's privacy and confidentiality in accordance with legal and ethical standards is the core of all processes within the laboratory. We ensure full compliance with GDPR by implementing strict controls for accessing, processing, and storing patient data. This is achieved through;

- **Data Encryption**: Use encryption and secure systems for managing patient information and test results to prevent unauthorised access.
- **Staff Awareness**: All laboratory staff have acknowledged POL-GEN-085 Policy on Data Breach Protocols

4.6 Continuous Improvement through Patient and Staff Feedback

The Laboratory Management use feedback to continually refine and improve patient safety and care processes. As stated in section 2.4 above, Laboratory Management sincerely appreciate the time and effort taken to provide feedback on our laboratory management system. User's insights are invaluable to us as they help identify areas for improvement and innovation. All feedback received, is thoroughly reviewed and incorporated into our continuous improvement process. This allows us to enhance our systems, optimise workflows, and ultimately deliver a higher standard of service and patient care.

4.7 Establish External Collaboration and Compliance with Accreditation Bodies

The Laboratory Management ensures that the laboratory maintains the highest standards of patient safety and rights through external validation. This is achieved through;

- **Accreditation**: Both the Blood Transfusion and the Haematology Laboratories and the overall Quality Management System (QMS) are accredited to ISO 15189 to demonstrate the laboratory's commitment to quality and patient safety. The Mater Private Network is also accredited to the current JCI Standards.
- **Collaboration with Healthcare Providers**: We as a team, work closely with other healthcare providers (e.g., physicians, hospital administrators) to ensure that laboratory processes align with overall patient care plans. This is achieved through QUEST, MAB and others committee groups.

- **Benchmarking**: Regularly compare laboratory performance and safety practices with industry standards to identify areas for improvement. This is achieved through a robust External Quality Assurance programme across all laboratory departments.

4.8 Monitoring and Evaluation of Process Effectiveness

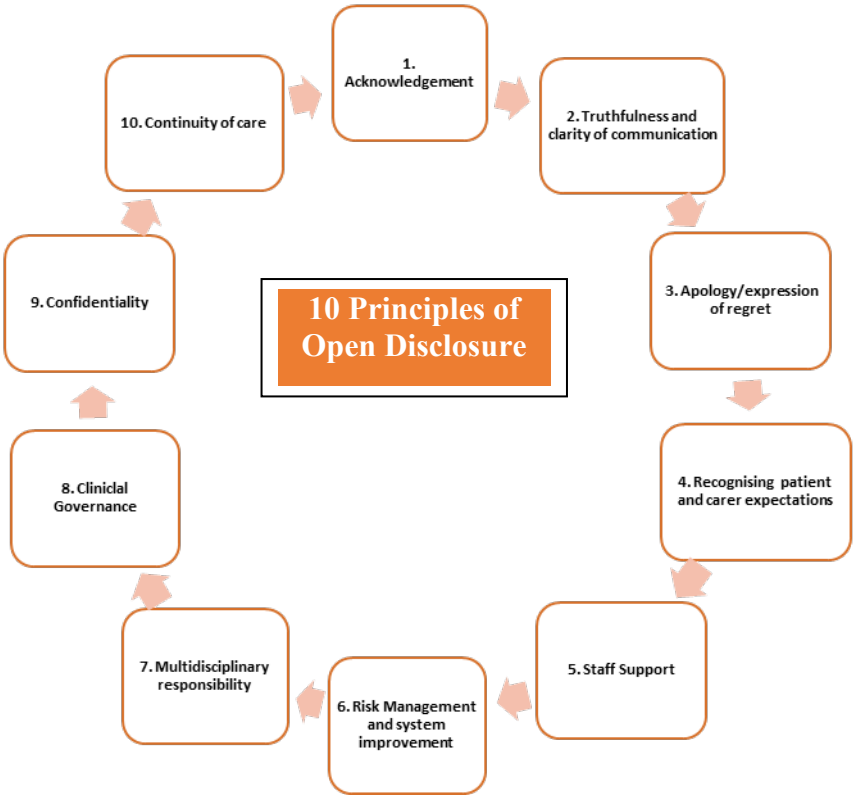
The Laboratory Management team regularly monitor the effectiveness of the implemented processes to ensure they prioritise patient well-being, safety, and rights. This is achieved through;

- Quality Indicators (QIs): The laboratory use the following Quality relating to patient safety:
  a) **Turnaround Times**
  b) **EQA Performance**
  c) **Rejection Figures**
  d) **Incident Close-Out**
  e) **Audit Performance**
- Regular review meetings are held to evaluate the performance the laboratory.
- Adjustments and Updates: Based on evaluation data, the laboratory aim to update and refine processes, policies, and training to continuously improve patient outcomes.

4.9 Open Disclosure Policy

In compliance with the Patient Safety (Notifiable Incidents and Open Disclosures) Act 2023 and in keeping with the Mater Private's commitment to our patients, it is the policy of the Mater Private that patients/relevant person are communicated with in an open, honest, transparent, and empathetic manner following patient safety incidents and that they are provided with a sincere and meaningful apology in a timely manner in accordance with the 10 Principles of Open Disclosure below.

10 Principles of Open Disclosure that underpin the Open Disclosure Process:



5. MATER PRIVATE HOSPITAL PATHOLOGY SERVICES

The Pathology Laboratory is located on the ground floor to the left after the main reception of the Mater Private Hospital. The molecular laboratory is located on the lower ground floor opposite the lifts. All services undergo continuous review through quality assurance and audit activities. Both Blood Transfusion and Haematology Laboratories and the overall Quality Management System (QMS) are accredited to ISO 15189 (registration number 191MT) https://www.inab.ie/FileUpload/Medical-Testing/The-Mater-Private-Hospital-191MT.pdf and is in compliance with articles 14 and 15 of the EU Directive 2002/98/EC, thus assuring users of a consistently high quality service.

This manual is designed to give an overall view of the services available in the Pathology Laboratory at the Mater Private Network, Dublin. It is intended as a reference guide for all clinical users of the Pathology Laboratory. The MPN Dublin Pathology Laboratory is

composed of six departments, as follows: Microbiology, Blood Transfusion, Haematology, Biochemistry / Endocrinology, Histopathology / Cytology and Immunology / Serology. There is also a phlebotomy service available for both inpatients and outpatients. Point of Care testing is available in clinical areas. This guide is divided into sections, one for each of the disciplines within the Pathology Laboratory. Refer to the appropriate section for detailed advice.

The Pathology Department provides routine laboratory and emergency ("on call") service to the Mater Private Network, Dublin and a limited pathology service to the Sports Surgery Clinic Santry and to The Mater Private Network Cork. In addition, GPs may also use the services of the Laboratory, if required.

The Pathology Laboratory refers some tests (including rare and unusual tests) to external laboratories and this manual lists the requirements for those tests referred to external laboratories on an ongoing basis (See LF-GEN-0021 Register of Referral Laboratories). If a clinical user requires a test that is not detailed in this manual or is uncertain about some aspect of requesting or performing a test, they should contact the laboratory in advance of arranging the test.

Please note the laboratory will only claim conformity for the list of tests as detailed in the scope of accredited test registered under INAB Registration number 191MT, and excludes externally provided laboratory activities on an ongoing basis.

5.1 Information and Advice

This guide is divided into sections, one for each of the disciplines within the Pathology Laboratory. There is a wide range of pathology tests available - refer to the appropriate section of this manual for detailed advice, facts and guidance. For internal users, this manual is available on the Hospital Intranet. It is also available on the internet on www.materprivate.ie.

This Manual details the following:

- The Location of the Laboratory
- The Phlebotomy Service
- The various specimen containers
- Information necessary for the correct laboratory labelling of specimen containers
- The examinations available within the Laboratory
- A description of each discipline's repertoire within the Pathology Laboratory including turnaround times
- Availability of clinical advice
- Laboratory patients, user, and personnel feedback

5.2 Head of Pathology

General matters which relate to more than one department should be addressed to: The Laboratory Manager - Mr. Paul Kennedy (01 2481840 or paul.kennedy@materprivate.ie) or the Director of Pathology – Dr Niall Mulligan (ext. 8137 or nmulligan@materprivate.ie)

5.3 Consultant and General Advisory Service

A comprehensive range of investigative and advisory services are offered by the different departments within Pathology.

The Pathology Laboratory has Consultants for all Departments to provide appropriate clinical advice and expertise to the users of the service. These Consultants can be contacted, where required, for advice on the appropriate choice of examinations and their clinical indications, the limitations of examination procedures and appropriate test frequency. They also provide consultation, where required, on individual clinical cases and interpretation of laboratory examinations. If Pathology Consultants cannot be contacted at extension 8137, in cases of urgency, the relevant consultant can be contacted elsewhere through the hospital reception. All new consultants are sent a copy of WI-GEN-0025 "Mater Private Network Dublin Pathology Services Summary for New Clinicians" as part of induction.

Please note for general immunology advice, the Consultant Immunologist may be contacted. For advice specifically on serology testing, users may contact Consultant Microbiologist.

See Table 1 for list of Consultants within Pathology Laboratory

Table 1: Consultants within Pathology Laboratory

Position	Name
Laboratory Director	Dr Niall Mulligan
Consultant Haematologist (with responsibility for Blood Transfusion)	Dr Michael Fay
Consultant Haematologist	Dr Peter O'Gorman Dr Andrea Piccin
Consultant Immunologist	Dr Con Feighery
Consultant Biochemist	Prof Maria Fitzgibbon Dr Graham Lee Dr Paula O'Shea
Consultant Microbiologist	Dr Maureen Lynch, Dr Margaret Hannan, Dr Deirdre Brady, Dr Breda Lynch and Dr Ursula Nusgen - (6 monthly rota for lead consultant)

Position	Name
Consultant Histopathologist	Dr Niall Mulligan (Laboratory Director) Dr Ann Treacy (Lead) Prof Conor O'Keane Dr Ciara Barrett Dr Susie Conlan Dr Eamon Leen Dr John Aird Dr Owen MacEneaney Dr Deirdre Timlin Dr Neil Fennelly

5.4 Phlebotomy

The Phlebotomy Department is located on the ground floor of the Mater Private Network, Dublin to the right of the main reception desk. The Phlebotomy waiting area is accessible for wheelchairs and the Phlebotomy room has movable trolleys so as to enable the staff to make a workstation around wheelchair. A Phlebotomy inpatient service is available from 7am until 4.45pm Monday to Friday. There is also a phlebotomy inpatient service from 7am to 12 pm on Saturdays and Sundays/Bank Holidays. There is a "walk-in" Phlebotomy outpatient service with no appointment necessary, however a referral letter from a doctor is required. Outpatient phlebotomy services are available from 8am to 4.00pm Monday to Friday and Saturday 9am to 1.00pm by appointment only. For most routine laboratory procedures, consent can be inferred when the patient presents at phlebotomy with a referral request from a doctor and willingly submits to venepuncture. Patients in a hospital bed can refuse venepuncture. Contact Phlebotomy on 8858165 for details of the service provided and the price charged for each test at the outpatients department.

5.4.1 Process for Booking Appointments for Phlebotomy

Patients wishing to book a blood test can do so by phoning 8858739 or emailing laboratory administration@materprivate.ie. The patient attends Phlebotomy at appointed time, is registered, invoiced and receipted. The blood sample is taken by Phlebotomist and sent to the Laboratory for testing. An encrypted report is emailed to patient. A copy may be sent to the patient's doctor if requested.

5.4.2 General Practice

General Practitioners may send appropriately packaged patient blood specimens by post/courier or they may ask the patients to attend the phlebotomy department with a referral letter.

5.5 Times of Service Availability

The routine working hours of the Pathology Department of the Mater Private Hospital are as follows:

Discipline	**Monday to Friday**	**Saturday**	**Contact Numbers**
Laboratory Office	8am to 6 pm	N/A	8138/8139
Biochemistry/Endocrinology	8am to 6 pm	9am to 12.30pm	8134
Haematology	8am to 6 pm	9am to 12.30pm	8132
Histology	8am to 5 pm	No service.	8136
Microbiology	8am to 6 pm	9am to 12.30pm	8133
Molecular Microbiology	8am to 6 pm	N/A	1898/8133
Blood Transfusion	8am to 6 pm	9am to 12.30pm	8131
Immunology	8am to 5 pm	No service	8140
Phlebotomy Inpatient	7am to 4.45pm	7am to 12pm	8165
Phlebotomy Outpatient	8am to 4.00pm	9am to 12pm by appointment	8166

Discipline	Monday to Friday	Saturday	Contact Numbers
Specimen Reception	8am to 5pm	9am to 12.30pm	8281

Table 2: Routine Working Hours within the Pathology Laboratory

Outside of routine working hours, an emergency service is provided (on-call) as follows:

Monday to Thursday: 6pm to 8am

Friday 6pm to 9am

Saturday: 12.30pm to 9am Sunday

Sundays and Bank Holiday Mondays: 9am to 8am the following day

Sundays of Bank Holiday: 9am to 9am

See individual department sections for repertoire of tests provided on-call.

There is a porter delivery service on Saturdays. It is essential that specimens for analysis arrive in the laboratory before 10.00am.

6. SPECIMEN HANDLING

6.1 Consumables

Each ward is responsible for stock management of consumable supplies which can be obtained from stores during working hours.

Stores supply the following:

- Plain swabs
- Copan Dual swabs for VRE screening
- UTM for COVID / Influenza / Respiratory pathogen testing (small supply retained for emergency testing in laboratory)
- Containers for sputum and mid-stream urines
- All tubes for blood collection

- Biopsy vials containing formalin. (Refer to the histology section of this manual for advice on the care necessary with formalin).

The Laboratory supplies the following:

- Timed urine collection containers, which may contain no preservative (plain) or 20ml of 0.5M molar hydrochloric acid as necessary for various investigations.
- Histology request cards and pots, with and without formalin, in a variety of sizes.
- Porphyrin containers
- Blood culture bottles
- Collection kits for Chlamydia/Gonorrhoea testing
- Specimen bottles for Quantiferon testing
- Swabs for viral investigations and transport swabs

6.2 Laboratory Labelling of Specimen to allow Unique Identity of the Patient

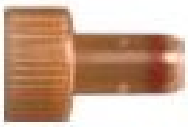
Each test(s) requested by a clinician, generates a unique ordercom laboratory label from PERL containing the patient demographics, the test(s) requested, a unique specimen number, the tube type, the date and time collected and the following:

- Forename & Surname
- Date of Birth
- Medical Record Number
- Account Number
- Gender
- Date of specimen collection
- Priority Status – when Urgent

NOTE: Histology samples will have an addressograph laboratory label on the request card with all specimen details logged electronically. Specimen pots should be clearly labelled with PERL labels as on request card and identified as A, B, C etc.

6.3 Specimen Collection-Order of Draw

The monovette system of drawing blood from patients is used. This consists of either 1 inch long, 21 & 22 gauge sterile needles and safety multifly set and monovette bottles, both manufactured by Sarstedt. Blood monovettes are sterile tubes of various sizes, the insides of which may or may not be coated with an anticoagulant, (see Table 3 below for order of draw):

COLOR CODE LINKED TO PERL LABEL		ORDER/ TUBE TYPE	SPECIMEN PREPARATION PROCESS/ INVESTIGATIONS
	**BCA and BCAN**	**1ST Blood Culture BCA Green- Aerobic BCAN Orange- Anaerobic**	• One set of blood cultures includes aerobic and anaerobic • Collect Aerobic bottle first, followed by Anaerobic bottle • Fill each bottle with 5 to 10mls. of blood
	**WHITE (7.5ml) & WHITE 4.9**	**2ND Serum**	• Stand upright once drawn • All Drug Levels • Immunology
	**BROWN (7.5ml) & BROWN 4.9**	**3RD Serum Gel**	• Stand upright once drawn • All Biochemistry
	**GREEN**	**4TH Sodium Citrate Coagulation**	• **Completely fill tube to line indicated on label** • INR, PT, APTT, FIBRINOGEN, D DIMERS
	**ORANGE**	**5TH Lithium Heparin Gel**	• Tube must be full • FSH, LH, ESTROGEN, PROGESTERONE
	**BT PINK (7.5ml)**	**6TH EDTA For Blood Transfusion**	• **HANDWRITTEN (in the event of PERL downtime process)** • All Blood Transfusion

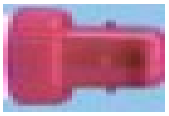
COLOR CODE LINKED TO PERL LABEL		ORDER/ TUBE TYPE	SPECIMEN PREPARATION PROCESS/ INVESTIGATIONS
	**PINK**	**7TH** **EDTA 2.7ml**	• Tube must be full • FBC, HBA1C, PTH, BLOOD FILM, RETICULOCYTES
	**DARK RED**	**8TH** **ThromboExact 2.7ml**	• Tube must be full • THROMBOCYTOPENIA
	**PURPLE**	**9TH** **ESR**	• **Completely fill tube to line indicated on label** • ESR
	**YELLOW**	**10TH** **Fluoride EDTA**	• **Completely fill tube to line indicated on label** • GLUCOSE, OGTT
	**Grey** **Green** **Yellow** **Purple**	**11TH** Quantiferon	• **1ml in each tube (fill line)** • **1st Grey,** • **2nd Green,** • **3rd Yellow** • **4th Purple** Quantiferon
	**Blood gas aspirator**	**12TH** **Blood Gases**	**1.5ml** • Venous • Arterial • Lactate

Table 3: Order of Draw *Ref.: EX-PHL-0001*

6.4 Specimen Collection and Confirming the Identity of the Patient

The person collecting the specimen (phlebotomist, nursing staff or house doctor) must identify the patient verbally and must also check and scan the patient's wristband with the phlebotomy handheld device and confirm patient's details before progressing.

1. The patient must be informed of the reason for collection of the specimen.
2. For most routine laboratory procedures, consent can be inferred when the patient presents at phlebotomy with a referral request from a doctor and willingly submits to venepuncture. Patients in a hospital bed can refuse venepuncture.
3. The phlebotomist confirms with the patient that they meet the pre-examination requirements (e.g. fasting status, medication status, specimen collection at predetermined time etc.). Note: Fasting for 12 hours is required for fasting bloods(e.g. Lipid Profile, Glucose)
4. The patient must be verbally identified (where possible) by asking their forename, surname and date of birth.
5. It must be guaranteed that the identity bracelet contains the correct forename, surname, date of birth and a unique hospital number.
6. Once the patient has been confirmed, a list of samples to be drawn will be displayed on the handheld device. Once the samples required are confirmed, the laboratory labels will print which can then be attached to the respective specimen tubes. This process is defined in detail in CML-PHL-0001, "Blood sampling in the phlebotomy department".

6.4.1 Blood Cultures

1. Obtain 2 blood culture bottles and 1 blood culture pack from the Specimen Reception area of the Pathology Laboratory.
    - *Note:* The BacT/Alert 3D blood culture system is used in the Mater Private Network, Dublin. Two bottles are used; FA for aerobic and facultative anaerobic microorganisms and FN for anaerobic microorganisms. FN contains contain 32ml of complex media and 8ml of a charcoal suspension. Bottles contain an atmosphere of nitrogen under vacuum. FA contains 22ml of complex media and 8ml of a charcoal suspension, Bottles contain an atmosphere of CO2 in oxygen. It is suitable for the isolation of aerobic, anaerobic organisms and fungi.

2. Prior to use, the BacT/ALERT FN/ FN Culture Bottles should be examined for evidence of damage or deterioration (discoloration). Bottles exhibiting evidence of damage, leakage, or deterioration should be discarded. The media in undisturbed bottles should be clear, but there may be a slight opalescence or a trace of precipitate due to the anticoagulant SPS.
3. Check Name and D.O.B. with patient and same details including MRN on patients ID band.
4. Prior to touching a patient, hand hygiene must be completed by the phlebotomist, by washing hands or using alcohol hand rub (moment 1 - before patient contact). Identify a suitable vein (usually on the arm) from which to draw blood from the patient. Clean hands.
5. Open sterile pack and set up sterile field, attaching the devices needed together in preparation for the procedure
6. Apply the single use Tourniquet above the blood-sampling site and swab the skin over the vein vigorously for 1 minute with a 2% chlorhexidine in 70% alcohol single use sponge/swab (chloraprep). Allow to dry for 30 seconds.
7. Remove the flip-lid seal from the blood culture bottles and swab the rubber stopper thoroughly with sanicloth CHG 2% swab. Clean hands using alcohol hand gel or by washing them and Apply - sterile gloves. Then using aseptic non-touch technique, take a sterile butterfly safety device, Insert the butterfly into the vein of the patient, taking care not to contaminate, repalpate or touch the needle insertion site and obtain up to a 10ml blood specimen (4ml for a paediatric bottle). If you need to palpate the vein again it's important to remove gloves, re-clean hands and apply a new set of sterile gloves.
8. Place the collection cap over the blood culture bottle and fill to the required level. Then repeat for bottle two. Always collect aerobic (green) before anerobic (orange). (If you need to collect the blood via a syringe and not from the closed circuit you should enter the blood into the anerobic bottle first and then the aerobic bottle).

9. Once the blood is collected, disconnect blood culture section and proceed to take any blood samples needed
10. Remove the tourniquet first, Then carefully remove the butterfly, ensuring the safety cover is applied as you remove it
11. Place a plaster or dressing over the blood-sampling site.
12. Place used needles and sharps into the CinBin provided. Any other clinical waste must be disposed of directly into yellow risk waste bin.
13. Remove gloves, clean hands.
14. Label the blood culture blood with the ordercom barcode laboratory label.
15. If an investigation for endocarditis is required a specimen comment of 'Query Endocarditis' must be noted in the Specimen comment section.

Note: Never send Blood culture bottles in the Chute system.

16. Outside of routine working hours: Please bleep a porter as soon as possible after collecting the specimen. The porter will transport the blood culture bottles to the laboratory and load the bottles on to the Bac-T alert system. **DO NOT REFRIGERATE**

6.5 Checking that the Patient is Appropriately Prepared

The appropriate preparation of the patient for the requested test and the correct specimen collection is the responsibility of the individuals requesting / collecting the specimen.

6.6 Checking that the Specimen Container is Laboratory Labelled Correctly

Having positively identified the patient, the person collecting the specimen (phlebotomist, nursing staff or house doctor) must collect the specimen and correctly label the container and request card (for histology) with the unique ordercom barcode label. It must be ensured that there can be no confusion regarding the identity of the patient or the specimen.
This is the first step in positive specimen identification. The identification data affixed to the specimen / container at source remains with that specimen throughout analysis.

It is critical the correct tests ordered are placed on the appropriate anti-coagulant tube. Each specimen label indicates which tube it should be affixed as described in *EX-PHL-0001 "PHLEBOTOMY TUBE GUIDE AND ORDER OF DRAW".*

6.7 Ensuring that the Specimen is Collected Correctly

Always ensure the blood is collected into the appropriate tube with the correct anticoagulant, if any, and that where possible, when using the "monovette"system, that the specimen container is filled to the correct volume to allow for anticoagulant blood mix ratio. In the event that a test requested is not listed, the relevant laboratory is contacted, as some of the less common tests require special collection and handling procedures.

Ref.: CM-PHL-0001 Blood Sampling in the Phlebotomy Department

Ref.: CM-PHL-0002 Glucose Tolerance Test

Please note:

1. Blood cultures must be sent to the laboratory within four hours of collection to be loaded onto the Bac-T Alert automated system.
2. Histology specimens in buffered formalin should be stored at room temperature. Do not refrigerate.
3. Specimens for potassium deteriorate less rapidly at room temperature than when refrigerated.
4. Specimens requiring immediate preparation should be collected within normal hours.
5. Ensure safe disposal of materials used in specimen collection in the nearest CINBIN.

6.7.1 Type of Specimen and, where appropriate, Anatomical Site of Origin

The specimen type should be recorded on all requests for each of the Pathology Departments. However, in Microbiology & Histology, the specimen type and anatomical site of origin must be recorded to ensure that appropriate tests are performed; this is important in the interpretation of results and is an important step in the audit trail.

6.7.2 Investigations Requested

All tests available to be ordered and provided in house are listed in PERL and are available in this Laboratory User Handbook. All referral laboratory tests are listed on PERL and on laboratory form LF-GEN-0021 Register of Referral Laboratories and Consultants which is also available on Q-Pulse. Add-on tests can be requested directly on PERL and depending on the specimen type and time frame, see individual departmental sections in this User Handbook for information on specimen stability. Each request accepted by the laboratory for examination shall be considered an agreement.

6.7.3 Relevant Clinical Information

Clinical detail can be added in the optional field on PERL when ordering the test by the medical team. This is to ensure that informed clinical and technical advice and clinical interpretation can be provided if applicable.

6.7.4 Identification of Priority Status

1. Urgent requests must be restricted to those necessary for the immediate clinical management of the patient.
2. In case of doubt, the clinician must make direct contact with the Laboratory.
3. The clinician and laboratory must agree:
   - Which tests are necessary
   - The target time for test completion/when results will be available on PERL.
   - Where reports are to be directed
4. In the case of an urgent request, the test must be ordered as urgent on PERL, which will generate an "S" on the specimen tubes instead or "R" for routine. Example 0114:H00011S.
5. Failure to make verbal contact with the laboratory outside routine working hours will result in delay and possible specimen degradation.
   All requests from UCC/ED/Day Oncology have a red line on the barcode laboratory el indicating these as urgent status.

6. Urgent requests for blood or blood products must be preceded by a telephone call from the requesting Clinician or Healthcare Professional informing the Medical Scientist what product and quantity is required and the time frame in which it is required. If red cells are required urgently before the time required for crossmatch, they may be issued following the emergency protocol in the laboratory at the requesting Clinician's discretion.
7. Transport arrangements are the responsibility of the requesting ward.
8. In exceptional circumstances urgent biopsies requiring histological opinion may be processed rapidly but only after consultation with the Histopathologist. (See Section 9)

6.8 Laboratory Labelling for Danger of infection: Hepatitis Risk, HIV Risk and Other Hazardous Pathogens

All specimens must be treated as potentially infectious and universal precautions must be taken by all staff.

6.9 Category A Pathogens

Only laboratory oratories, which have notified the Health and Safety Authority (H.S.A), may provide a diagnostic service for listed pathogens. In cases where a listed pathogen is discovered unexpectedly, the HSA must be notified immediately.
All samples from suspected TB patients must be notified to laboratory staff.

6.10 Specimen Transport Bags

Barcode laboratory labelled specimens must be transported to the Pathology Laboratory in a sealed transport biohazard bag and must not be used more than once. In the case of Microbiology, batches of samples are received from Santry Sports Surgery Clinic and MPH Cork, packaged as detailed above, using secure transport boxes. Histology samples received from Santry Sports Surgery Clinic and MPN Cork are packaged as detailed above, using secure transport boxes.

Liquid samples containing possible respiratory pathogens (Influenza / RSV and SARS-CoV-2) must be further placed in a sealable biohazard bag, and transported individually.

The use of the above means of transport ensures the following:

1. Limiting all unnecessary hand contact with specimen containers;
2. Making it easy to identify a leaking container among a batch;
3. Preventing a leaking container from contaminating other containers, request forms, the hands of the person sorting a batch, and the immediate environment.
4. Special secure specimen transport carriers must be used, such as boxes or deep-sided trays. They must not be over-filled.
5. The specimen transport boxes or trays must not be used for any purpose other than carrying specimens.
6. The boxes or trays must be made of a smooth impervious material such as plastic or metal which can be easily disinfected and cleaned and must retain liquid in the event of leakage of a specimen.
7. The boxes or trays must be disinfected and cleaned after each week in use and whenever contaminated.

6.11 Transport

Most analytical work takes place in the Pathology Laboratory. Some specimens are sent to outside laboratories (See LF-GEN-0021 Register of Referral Laboratories).
Nurses, porters and phlebotomists undertake transport of reports and consumables to and from Pathology. Transport of specimens to the laboratory is mainly via the pneumatic chute system. Blood cultures and Respiratory specimens (SARS-CoV-2 (COVID-19) and Influenza testing) must never be sent via the pneumatic tube system and urines should not be sent via this system out of hours. Transport boxes are available in the laboratory and wards to safely

transport repertory specimen to the laboratory. All other urgent specimens are transported via the pneumatic chute system. The relevant department should be contacted to alert the laboratory staff to the pending receipt of an urgent specimen in Specimen Reception. **See individual departmental sections of this handbook for specimens that MUST be delivered to the Laboratory within a certain time period.**

Ref.: LF-GEN-0021 Register of Referral Laboratories

6.12 Reception of Specimens in the Laboratory

Specimens arrive to the laboratory via the pneumatic chute system or are hand delivered. The specimen transportation systems ensure the timely arrival of specimens in the optimal condition, to the correct destination, and in a manner that does not pose a threat to the health and safety of persons, property and the environment and is in compliance with relevant regulations. They are dispatched to the relevant departments for analysis or sent to referral laboratories. Transport is undertaken by Phlebotomists, Medical Staff, Nursing Staff, Administration Staff, G.P. Patients, Courier (road and air), Rail System, Post, Laboratory Staff, and Hospital porters and clerks.

Samples that should **not** be sent in the "chute" include the following….

- Specimens that are not easily repeated e.g. CSF's or Bronchial washings
- Any Histology specimens
- Units of Blood
- Blood Culture bottles
- Blood Gases
- Covid Swabs

Ref.: EX-GEN-0043 Aerocom AC3000 Service Manual & SS-HS-048 Safety Statement Mater Private Network

Urgent requests must be brought to the attention of the relevant laboratory staff.

Outside of routine opening hours, the Medical Scientist on-call must be contacted by reception or security and will deal with the urgent requests. Portering staff deal with the following:

- Collection, transportation & loading of blood cultures to the laboratory out of routine hours.
- Microbiological specimens in the relevant fridge.

6.13 Common Sampling Issues

For blood specimens the 'Monovette' system is preferred.

Some common problems and errors are:

1. Failure to seal the urine container properly resulting in sample leakage. These samples will be rejected by the laboratory and can have an affect on other samples.
2. Use of the wrong specimen container - refer to the relevant department for details.
3. Contaminating a 'clotted blood' tube with EDTA from a red top tube, which affects iron, calcium and potassium etc.
4. Collection of a specimen from an arm with a 'drip'.
5. Ejection of blood through a needle causing haemolysis.
6. Failure to gently mix, dissolve and distribute anticoagulants and preservatives.
7. Failing to prepare the patient correctly e.g. fasting, collection at the wrong time of day, day of menstrual cycle, gestational age etc.
8. Failing to deliver the specimen to the Laboratory in the time required for the investigation. Refer to the relevant department for further information.
9. Failure to keep the gel biochemistry specimen containers upright until the specimen has clotted.

6.13.1 Non-Compliant Laboratory Specimen Containers

It is laboratory policy that unlabelled specimens will not be processed and will be disposed of on receipt.

However, some are particularly critical and invasive e.g. CSF's, bronchial washings, histology specimens, blood gases, pleural aspirates and knee fluids, and may not be easily repeated. Therefore, it is laboratory policy to attempt to resolve any discrepancies on these specimens or containers before a specimen is rejected.

In the case of **unlabelled critical/invasive specimens, which cannot be repeated** (e.g. histology/CSF) proceed as follows:

1. Contact must be made with the requesting clinician.
2. The clinician/requester must be requested to identify and label the specimen properly and to resolve any discrepancies.
3. The clinician/requester must also complete LF-GEN-0028 Non-Compliance Disclaimer Form. The fact that specimen/patient details have been amended is recorded as a comment on LIMS and the amendments that have been made and confirmed and by whom.
4. Histology: This LF-GEN-0028 Non-Compliance Disclaimer Form is scanned & uploaded against the non-conformance as an attachment on the QRM on PERL (Please note on LF-GEN-0028 Non-Compliance Disclaimer Form the laboratory non-conformance number associated with this event).
5. If the demographics cannot be confirmed the specimen is rejected.

Ref.: LS-SR-0001 Specimen Reception Procedure

Ref.: LF-GEN-0028 Non-Compliance Disclaimer Form

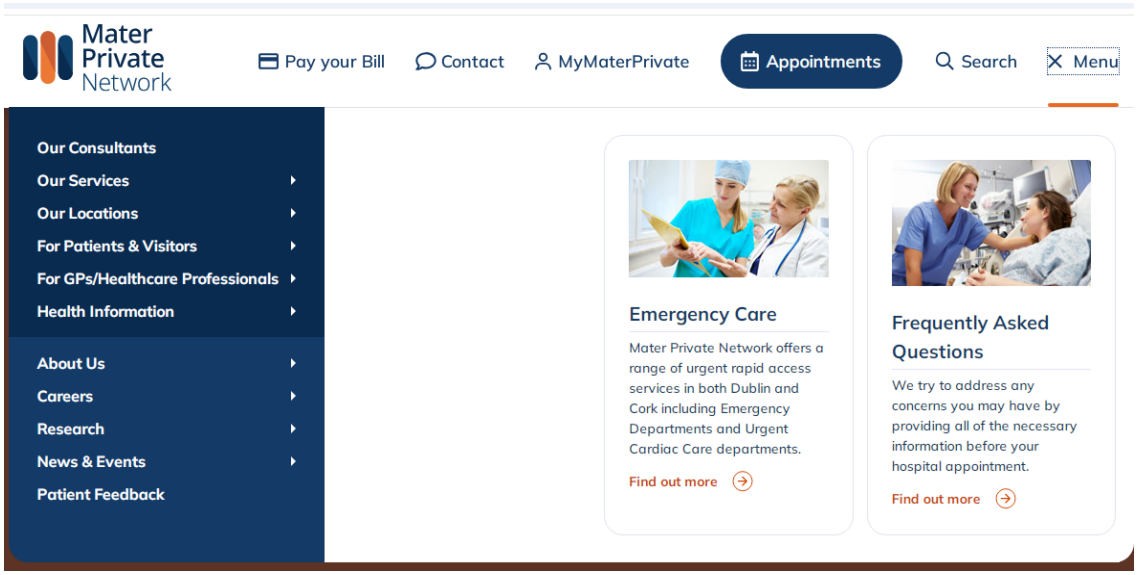
NOTE: Any non-conformances associated with specimen containers, request forms, specimen collection, handling and transport will be recorded on the QRM on PERL as a non-conformance.

6.14 Laboratory Patients, User, and Personnel Feedback

The Laboratory Quality Co-ordinator distributes an annual questionnaire to the Wards &/or Consultants who use the service of the Pathology Laboratory of the MPH. The aim of the

user satisfaction surveys or clinical audits is to achieve continuous improvement in all aspects of the pathology laboratory resulting in improved clinical effectiveness. Complaints, comments or other feedback may also be received from patients, staff or other parties throughout the year either directly to the Laboratory Manager (01 2481840 or paul.kennedy@materprivate.ie), Quality Coordinator (Ext 8346 or laboratory quality@materprivate.ie), any member of staff or via QRM on PERL as non-conformances. At Mater Private Network Dublin, we put great care into ensuring that each patient experience is a positive one. But we don't always get it right. We believe that effective, proactive handling of patient feedback allows us to demonstrate the value we place on their opinion, and enables us to address issues that need addressing. Any Patient Feedback relating to the laboratory is also collated from Hospital Quality or the Patient Liaison Team. This feedback is uploaded onto the QRM in PERL and investigated fully.

The laboratory is committed to supporting patients and laboratory users to provide helpful information to aid the laboratory in the selection of the examination methods, and the interpretation of the examination results. This is achieved through the use of a Patient Feedback forum on the Mater Private Network website www.materprivate.ie, patient feedback section or by emailing Laboratory.Feedback@materprivate.ie.



We sincerely appreciate the time and effort taken to provide feedback on our laboratory management system. Your insights are invaluable to us as they help identify areas for improvement and innovation. Rest assured, all feedback will be thoroughly reviewed and incorporated into our continuous improvement process. This allows us to enhance our systems, optimise workflows, and ultimately deliver a higher standard of service and patient care. Your input plays a crucial role in shaping a more efficient and reliable laboratory management system with the Mater Private Network Dublin, and we thank you for contributing to this ongoing journey of excellence.

This email address is managed by the Laboratory Quality Co-ordinator and the Laboratory Manager.

6.15 Reports

Each department has its own distinctive reports. Wards within the hospital have direct access to patient results on PERL once authorised. Please check status of results on PERL prior to contacting the laboratory by phone. Phoning of the laboratory for results is discouraged due to the risk of transcription errors. However, it is the policy of the Pathology Laboratory to phone urgent requests and when specific parameters have reached critical alert values. "Critical alert values" are when examination parameters are significantly outside the normal reference range and may indicate a high risk of a life threatening condition. Clinical personnel responsible for the patient care will be immediately notified when examination results for critical properties fall within established "critical intervals". This includes results received on specimens sent to referral laboratories.

The Critical alert values are documented in each individual department's specific section of this manual.

Ref.: POL-GEN-032 Verbal and Telephone Orders/ Critical Test Results Policy

6.16 Reference Ranges

The manufacturer of the reagents and the technology utilised to carry out the examination defines the reference ranges. Where appropriate, these reference ranges are age and gender related. In certain situations, reference ranges may be taken from reference books or the laboratory establishes its own reference ranges. Any changes in reference ranges are notified to the users prior to implementation and for a certain period of time on the report. The laboratory calculates the "uncertainty of measurement" where applicable. These estimates of uncertainty of measurement are available to laboratory users on request.

6.17 Patient Confidentiality

The confidentiality of patient records forms part of the ancient Hippocratic Oath, and is central to the ethical tradition of medicine and health care. The Mater Private Network has a documented procedure "Hospital Ethical Framework" to ensure that the confidentiality of patient information is maintained at all times. This policy is distributed to all laboratory staff and must be read and acknowledged as par of the laboratory's staff induction process. Access to and from the Pathology Laboratory and to the Laboratory Information Management System are safeguarded against unauthorised access.

Ref.: POL-GEN-069 Hospital Ethical Framework"

7. BIOCHEMISTRY/ENDOCRINOLOGY

7.1 Repertoire of the Tests

The following table contains a repertoire of the tests assayed in the Biochemistry Department. Many other tests are carried out or referred to appropriate specialist laboratories when required.

Test	Order code	Sample Type	Special Precautions	TAT	Adult Reference Ranges
Alanine Amino-transferase	**ALT**	**Serum-Gel 7.5ml**		**2.5hrs or 70 Minutes STAT**	**M <41 IU/L F <33 IU/L**
Albumin	**ALB**	**Serum-Gel 7.5ml**		**2.5hrs or 70 Minutes STAT**	**<14yr 38-54 g/L 14-18yr 32-45 g/L >18yr 35-52 g/L**
Alkaline Phosphatase	**ALP**	**Serum-Gel 7.5ml**		**2.5hrs or 70 Minutes STAT**	**<10yr 142-335 IU/L 10-<13yr 129-417 IU/L 13-15yr M 116-468 IU/L 13-15yr F 57-254 IU/L 15-17 M 82-331 IU/L 15-17 F 50-117 IU/L 17-19 M 55-149 IU/L 17-19 F 45-87 IU/L >19 M 40-129 IU/L >19 F 35-104 IU/L**
Amylase	**AMY**	**Serum-Gel 7.5ml**		**2.5hrs or 70 Minutes STAT**	**28-100 IU/L**

Test	Order code	Sample Type	Special Precautions	TAT	Adult Reference Ranges
Arterial Blood Gas	ABG	ABG Heparin Syringe	Ensure there are no air bubbles and analyse immediately. Use Lithium Hep. Syringe	30 Minutes	PH: 7.35 -7.45 kPa PCO2: 4.5-6.0 kPa PO2: 11.0-14.5 kPa Std. Bicarb: 22.4-25.8mmol/L O2 Sat: 95-98% Base Excess -2.3-+2.3 mmol/L
Aspartate Amino-transferase	AST	Serum-Gel 7.5ml		2.5hrs or 70 Minutes STAT	M <40 IU/L F <32 IU/L
Bicarbonate	ECO2	Serum-Gel 7.5ml		2.5hrs or 70 Minutes STAT	22-29 mmol/L
Calcium	CA	Serum-Gel 7.5ml		2.5hrs or 70 Minutes STAT	2-12yr 2.20-2.70 mmol/L 12-18yr 2.10-2.55mmol/L 18-60yr 2.15-2.50mmol/L 60-90yr 2.20-2.55mmol/L >90yr 2.05-2.40 mmol/L
Calcium-Adjusted	Corr	Calculation	Calculation based on Albumin/Calcium results.	2.5hrs or 70 Minutes STAT	Not calculated for Alb<20 g/L Reference range same as calcium.
Cancer antigen125	C125	Serum-Gel 7.5ml		Daily (Weekdays)	0-35U/ml
Cancer antigen153	C153	Serum-Gel 7.5ml		Daily (Weekdays)	<26.4 U/ml

Test	Order code	Sample Type	Special Precautions	TAT	Adult Reference Ranges
Carcino-embryonic antigen	**CEA**	**Serum-Gel 7.5ml**		**Daily (Weekdays)**	**0.0-5.2 µg/l**
Chloride	**CL**	**Serum-Gel 7.5ml**		**2.5hrs or 70 Minutes STAT**	**95-108 mmol/L**
Cholesterol	**CHOL**	**Serum-Gel 7.5ml**		**2.5hrs**	**<5.0 mmol/L optimal**
Cortisol	**CORL**	**Serum-Gel 7.5ml**		**Daily (Weekdays) 90mins STAT**	**133-537 nmol/L for morning samples (6-10am)**
C-Reactive Protein	**CRP**	**Serum-Gel 7.5ml**		**2.5hrs or 70 Minutes STAT**	**0-5.0 mg/L**
Creatine Kinase	**CK**	**Serum-Gel 7.5ml**		**2.5hrs or 70 Minutes STAT**	**M=39-308 IU/L F=26-192 IU/L**
Creatinine	**CREA**	**Serum-Gel 7.5ml**		**2.5hrs or 70 Minutes STAT**	**5-7yr 25-42 µmol/L 7-9yr 30-47 µmol/L 9-11yr 29-56 µmol/L 11-13yr 39-60 µmol/L 13-15yr 40-68 µmol/L F: 45-84 µmol/L M: 59-104 µmol/L**
CSF Protein & Glucose	**CSF**	**1.0ml CSF**	**Send to Laboratory immediately.**	**70 Minutes**	**15-45 mg/dL 2.22-3.89 mmol/L**

Test	Order code	Sample Type	Special Precautions	TAT	Adult Reference Ranges
Digoxin	**DGNA**	**Clotted 7.5ml (plain)**		**2.5hrs or 70 Minutes STAT**	**0.77-1.5 nmol/L**
eGFR	**eGFR**	**Calculation**	**Calculation based on the EPI 2009 formula**		**>120 ml/min**
Ferritin	**FERR**	**Serum-Gel 7.5ml**		**Daily (Weekdays)**	**M: 30 – 400ug/L F: 13 – 150 ug/L**
Folate	**FOL**	**Serum-Gel 7.5ml**		**Daily (Weekdays)**	**3.9 – 26.8 ng/mL**
Gamma Glutamyl Transferase	**GGT**	**Serum-Gel 7.5ml**		**2.5hrs or 70 Minutes STAT**	**M: 10-71 U/L F: 6-42 U/L**
Gentamicin	**GEN**	**Clotted 7.5ml (Plain)**		**2.5hrs or 70 Minutes STAT**	**Refer to Consultant Microbiologist**
Fasting Glucose	**GLU**	**Fluoride Oxalate Bottle 2.5ml**	**12 hour fast. Analyse as soon as possible. Blood sample must be received within one hour of venepuncture.**	**2.5hrs or 70 Minutes STAT**	**3.9-5.6 mmol/L**
Glucose Tolerance Test	**GTT**	**2 x 2.5ml bottles Fluoride Oxalate Bottle**	**See instructions for modified GTT testing.**	**2.5hrs**	**Fasting 3.9-5.6 mmol/L 2hrs pp <7.8 mmol/L**

Test	Order code	Sample Type	Special Precautions	TAT	Adult Reference Ranges
Haemoglobin A1C	**HBA1 C**	**Whole Blood (EDTA) 2.5mls**	**Use EDTA Sample**	**Daily (Weekday)**	**20-42 mmol/mol**
High Density Lipoprotein	**HDL**	**Serum-Gel 7.5mls**		**2.5hrs**	**>1.00 mmol/L Optimal**
Hs-Troponin T	**TRO**	**Serum-Gel 7.5ml**		**2.5hrs or 75 Minutes STAT. All locations**	**0-14 ng/L Female 0-22 ng/L Male Values > 300 ng/L indicates a significant degree of myocardial damage, which may be consistent with MI. Values 22-300 ng/L In patients with symptoms of ACS requires Clinical Correlation.**
Human chorionic gonadotropin beta	**BHCG**	**Serum-Gel 7.5mls**		**Daily or 90 mins STAT**	**<5 IU/L Can be up to 9 in menopausal woman due to pituitary secretion**

Test	Order code	Sample Type	Special Precautions	TAT	Adult Reference Ranges
Inorganic Phosphate	**PHOS**	**Serum-Gel 7.5ml**		**2.5hrs or 70 Minutes STAT**	**4-6yr 1.05-1.80 mmol/L M:7-9yr0.95-1.75mmol/L F:7-9yr 1.00-1.80 mmol/L M:10-12yr 1.05-1.85 F:10-12yr 1.05-1.70 M:13-15yr 0.95-1.65 F:13-15yr 0.90-1.55 M:16-18yr 0.85-1.60 F:16-18 0.80-1.55 Adult 0.81-1.45 mmol/L**
Iron	**FE**	**Serum-Gel 7.5ml**		**2.5hrs**	**5.83-34.5 µmol/L**
Lactate	**LAC**	**ABG Heparin Syringe (venous/ arterial sample)**	**Analyse as soon as possible. Done @POCT ABL machine**	**30 Minutes**	**0.5-2.0mmol/l**
Lactate Dehydrogenase	**LDH**	**Serum-Gel 7.5ml**		**2.5hrs or 70 Minutes STAT**	**2-15yr 120-300 IU/L F: 135-214 IU/L M: 135-225 IU/L**
Low Density Lipoprotein	**LDL**	**Serum-Gel Cl 7.5mls**		**2.5hrs**	**<3.0 mmol/L optimal**
Lipoprotein (a)	**LPA**	**Serum-Gel Cl 7.5mls**	**Spin/separate/ freeze Analyse once a week**	**weekly**	**<75 nmol/L**

Test	Order code	Sample Type	Special Precautions	TAT	Adult Reference Ranges
Magnesium	**MG**	**Serum-Gel 7.5ml**		**2.5hrs or 70 Minutes STAT**	**6-12yr 0.70-0.86 mmol/L 12-20yr 0.70-0.91 20-60yr 0.66-1.07 60-90yr 0.66-0.99 >90yr 0.70-0.95 mmol/L**
Non-HDL Cholesterol	**NHDL**		**Calculated test**	**2.5hrs**	**<3.4 Optimal**
NTproB-type natriuretic peptide	**BNP**	**Serum-Gel 7.5mls**		**2.5hrs or 70 mins STAT**	**<125 pg/ml**
Potassium	**K**	**Serum-Gel 7.5ml**		**2.5hrs or 70 Minutes STAT**	**3.5-5.3 mmol/L**
Progesterone	**PROG.D**	**Serum-Gel 7.5ml**		**Daily**	**Follicular: 0.2-0.6 nmol/L Mid Cycle: 0.2-13 nmol/l Luteal: 13-46 nmol/l Post Menopause: 0.2-0.6 nmol/l**
PTH	**PTH**	**Whole Blood (EDTA) 2.5mls**	**Spin/separate/ freeze Analyse once a week**	**weekly**	**1.6-6.9 pmol/L**
SHBG	**SHBG.D**	**Serum-Gel Clotted 7.5ml**		**Daily**	**Male: 20-49yr 18.3-54.1nmol/l Male:>50yr 20.6-76.7 1nmol/l Female:20-49yr 32.4-128nmol/l Female: >50yr 27.1-128nmol/l**

Test	Order code	Sample Type	Special Precautions	TAT	Adult Reference Ranges
Sodium	NA	Serum-Gel Clotted 7.5ml		2.5hrs or 70 Minutes STAT	133-146 mmol/L
Synacthen	SST	Serum-Gel 7.5ml	See section 4.13.3	Daily (Weekdays)	>450 nmol/L
Testosterone	TEST.D	Serum Gel 7.5ml		Daily Weekdays	Male: 20-49yr 8.6-29nmol/l Male: >50yr 6.7-25.7nmol/l Female: 20-49yr 0.3-1.7nmol/l Female:>50yr 0.1-1.42nmol/l
Thyroid Simulating Hormone	TSH	Serum-Gel 7.5ml		Daily (Weekdays)	0.270-4.45 mIU/L
Thyroxine Free T4	FT4	Serum-Gel 7.5ml		Daily (Weekdays)	12-22 pmol/L
Total Bilirubin	TBIL	Serum-Gel 7.5ml		2.5hrs or 70 Minutes STAT	M <24 µmol/L F <15 µmol/L
Total Protein	TP	Serum-Gel 7.5ml		2.5hrs or 70 Minutes STAT	60-80 g/L
Transferrin	TRNS	Serum-Gel 7.5ml		2.5hrs	2.0-3.6 g/L
Transferrin saturation	TSAT	Calculation		2.5 hrs	16-45%
Triglycerides	TRIG	Serum-Gel 7.5ml		2.5hrs	<1.7 mmol/L

Test	Order code	Sample Type	Special Precautions	TAT	Adult Reference Ranges
Uric Acid (Urate)	**UAC**	**Serum-Gel 7.5ml**		**2.5hrs or 80 Minutes STAT**	**M: 202-417 µmol/L F: 142-339 µmol/L**
Urea	**UREA**	**Serum Gel 7.5ml**		**2.5hrs or 70 Minutes STAT**	**18-60yr 2.14-7.14 mmol/L 60-90yr 2.86-8.21 mmol/L**
Urinary Amylase	**U.AMY**	**MSU Container**		**2.5 hrs**	**M: 16-491 U/L F: 21-447 U/L**
Urinary Calcium	**U.CA**	**24hr Plain Urine container/MSU**		**Daily (weekdays)**	**2.5-7.5 mmol/24hr**
Urinary Creatinine	**UCREAT**	**24hr container/ MSU container**		**Daily (weekdays)**	**M: 3540-24600 µmol/L F: 2550-20000 µmol/L**
Urinary Creatinine Clearance	**CCLR**	**24hr container**		**Daily (weekdays)**	**66-143 ml/min**
Urinary electrolytes (Na, K, CL)	**U24.NA U24.KU 24.CL**	**24hr/MSU container**		**2.5hrs**	**Interpret in conjunction with serum and water intake.**
Urinary Calcium/Creatinine ratio	**CCR**	**Calculation**	**Calculation**	**Daily**	**0.3-0.7 mmol/mmol**
Urinary Protein	**U24.PROT**	**24 hr urine container**		**Daily (weekdays)**	**<0.14 g/24 Hours**
Urinary Protein/creatinine ratio	**urPCR**	**Calculation**	**UK CKD guidelines**	**Daily (weekdays)**	**1-15mmol/L**

Test	Order code	Sample Type	Special Precautions	TAT	Adult Reference Ranges
Urinary Urea	**U.UREA**	**24hr Plain Urine container/MSU**		**Daily (weekdays)**	**428-741 mmol/24hrs**
Vancomycin **V PEAK** **V RANDOM** **V TROUGH**	 **VANCP** **VANCR** **VANCT**	**Clotted 7.5ml Sample to be taken 5 minutes pre-dose and 1 hour post dose**		**2.5hrs or 80 Minutes STAT**	**Refer to Consultant Microbiologist**
Venous Blood Gas	**VABG**	**ABG Heparin Syringe**	**Ensure there are no air bubbles and analyse immediately. Use Lithium Hep. Syringe**	**30 Minutes**	**PH: 7.35 -7.45 kPa** **PCO2: 6.0-8.0 kPa** **PO2: 8.0-11.0 kPa** **Std. Bicarb: 22.4-25.8 mmol/L** **O2 Sat: 85-90%** **Base Excess - 2.3-+2.3 mmol/L**
Vitamin B12	**VITB12**	**Serum-Gel 7.5mls**		**Daily (Weekdays)**	**197 – 771 pg/mL**
Vitamin D	**VITD**	**Serum-Gel 7.5mls**		**Daily (Weekdays)**	**>50 nmol/L**

Tube Type	Colour Key	Tests
Serum Gel (SST)		Most Clinical Chemistry Analytes except those stated below. Glucose if testing is not delayed > 1hr
EDTA tube		HbA1c, PTH
Fluoride Oxalate/CSF/MSU		Glucose (if testing delayed > 1 hr) MSU

ABG Syringe		ABG, Fluids for pH, ionised calcium.
Serum (Plain)/Urine		All Therapeutic drugs e.g. Gentamicin, Vancomycin, Digoxin

Table 4: Repertoire of Test Services:

Ref.: WI-BIO-0008 Biochemistry Reference Ranges

7.2 Sample Volume

It is preferable that blood tubes, especially those containing preservative, are filled to the stated capacity. This reduces the risk of insufficiency or interference from a preservative. We will always try to maximise the use of any sample, however where a sample is less than half full please indicate the tests that are of greatest importance.

The departments repertoire and test strategies have been evolved with due regard for clinical need, available resources etc. Please contact the senior member of the department for advice regarding availability and clinical application of Clinical Chemistry tests.

7.3 Turnaround Times (TAT)

Clinically urgent specimens will be processed within 70 minutes where possible. This includes the tests for Renal Profile, Liver Profile, CK, Bone Profile, Glucose, Magnesium, CRP, LDH, and NTproBNP. Troponin TAT is 75 minutes and this applies to all locations.

Any additional tests or necessary dilutions will delay the turnaround times. Samples from Urgent Cardiac Care and the Emergency Department are always treated as urgent. Urgent requests on samples outside these locations should be made by phone call to ensure a fast TAT within 70 minutes. Samples from Day Oncology, Emergency Department, Heart Centre Day Unit, X-ray and ITU are treated as priority and processed within 80 minutes where possible. Any additional tests requested beyond the critical tests stated above or necessary dilutions will delay the TAT. All other non-urgent samples and chemistry tests are processed within 2.5 hours. PTH samples TAT IS 7 days as only ran weekly. Tumour markers,

endocrinology and 24 hour urine samples are run in batches so the TAT is one day during routine hours unless an urgent request is made.

7.4 Processing of Fluids for Analysis

Fluids should be sent to the laboratory in a sterile universal container. Samples for glucose where testing is delayed > 1 hr must be sent in fluoride oxalate. Samples for pH should be transferred to a heparinised ABG syringe and sent to the Biochemistry laboratory immediately for analysis.

Pleural Fluids

All samples from suspected TB patients must be communicated to the laboratory by ward staff. This will also be recorded in the patient's chart. To view the special indicator in the chart;

- Go to the main menu,
- Click on Clinical then Patient Care Status Board
- Find patient using account number,
- Click Go To Chart, the Special Indicators tab is on the right-hand side of the chart.

This will help to minimise the exposure to the laboratory staff and allow samples to be handled in a safe manner.

FLUID TYPE	ANALYTES MEASURED
Cerebrospinal Fluid (CSF)	Glucose, Protein. Preserve glucose if testing is delayed by > 1 hour.
Pleural Fluid	Glucose, Protein, LDH, pH. pH only- as soon as fluid is collected, take a sample into blood gas tube and expel all air. **Serum should be tested for protein and LDH at the same time**. Preserve glucose if testing is delayed by > 1 hour.

FLUID TYPE	ANALYTES MEASURED
Peritoneal Fluid/Ascitic Fluid	Protein, LDH, Albumin, Amylase, Triglycerides. **Serum and Fluid samples should be taken concurrently**.
Knee Aspirate	Protein, LDH
Synovial Fluid	Protein, LDH
Wound or abscess drain	Protein
Drain Fluid(Robinsons)	Creatinine, Urea
Pericardial	Glucose, Protein, LDH, pH. pH only- as soon as fluid is collected, take a sample into blood gas tube and expel all air. Preserve glucose if testing is delayed by > 1 hour.

Table 5: Fluid Type & Analytes Measured

CSF's are always handled by Microbiology to maintain sterility for culture and sensitivity testing. An aliquot is then dispatched into Biochemistry with the corresponding Microbiology specimen number for protein and glucose analysis.

7.5 "Add –on" Tests and Sample Stability

7.5.1 Microbiology

Add-on tests for microbiology investigation can be requested when repeated sampling is not possible. Add-on tests are placed by phoning the laboratory on 8133. Most samples are stored for 1 week however add-ons should be requested as soon possible to insure sample availability and viability.

7.5.2 Blood Sciences

All add-on tests must be ordered on PERL by the ward clinical staff before the sample can be processed. The laboratory staff will then add the test to an available sample, if available as described in WI-GEN-029 Procedure to Add on a test in Haematology, Biochemistry or Immunology. The laboratory must be informed. A member of the biochemistry staff will assess whether the sample is still acceptable for analysis.

Likely sample stability for some common investigations:

- Samples received into the Biochemistry Department for routine testing are usually serum gel separated tubes.
- Clotted blood samples received into Biochemistry are labelled up and centrifuged within one hour.
- Some additional tests may be performed on this original sample within a 48 hour period. Blood samples are retained for 48 hours after a final report has been issued.
- Glucose should be measured in serum samples within 1 hr of venepuncture. Fluoride Oxalate tubes should be used if testing will be delayed > 1 hour.
- Tests that require specimens with special preservatives are:
    1. Glucose – Fluoride/Oxalate tube
    2. HBA1C – EDTA
    3. PTH - EDTA
- Urine samples are stable for three to four days depending on the test required when stored at 4 degrees Celsius.

7.6 On-Call Service Repertoire in Biochemistry

All routine Biochemistry tests are carried out during on-call hours with the exception of the following: Routine Endocrinology (TFT, Cortisol, PTH, Vitamin D), Tumour markers (TPSA, CA125, CA153, CEA), Haematinics (Ferritin, Folate, B12) and HbA1c.

Outside normal working hours the emergency service is covered by one Medical Laboratory Scientist on call, who is contactable by mobile phone through the main hospital reception/security. All tests authorised are available on PERL. Samples may be delivered to the laboratory via the pneumatic tube system.

7.7 Notes on Taking Blood Specimens for Biochemistry Tests

1. Correct labelling of specimens is mandatory with the ordercom barcode label. The label must be positioned straight on the sample tube in order for the analyser to read the barcode as described in LI-GEN-0011 Laboratory Specimen labelling instructions. Any poorly positioned labels may delay the processing of the sample.
2. 7.5mls blood (serum gel tubes) is the recommended volume for the majority of assays performed in the Biochemistry Department.
3. Contamination errors are most commonly caused by drawing blood from the arm of a patient which is already facilitating an I.V Line or pouring blood from one bottle into another e.g. EDTA into Heparin. Also the correct order of draw when taking samples.
4. For pH/Blood gases a pre-heparinised blood-gas monovette is recommended. Exclude all air, and mix in the heparin by rolling rapidly between the palms, to prevent clotting. If a sample clots it cannot be assayed and may cause a blockage on the blood gas analyser.
5. Blood gas samples with large air bubbles should not be sent to the Laboratory as pCO_2 and pO_2 are affected.
6. Blood gas samples should be analysed immediately. If this is not possible, analyse the sample within 30 minutes.
7. Samples for venous or arterial Lactate should be assayed on the blood gas analysers using blood gas heparin syringes within 30 minutes. If analysed within 30 to 90 minutes the result will come with a warning comment.
8. Blood gas specimens should not be sent in the pneumatic tube system or with needles attached to the Laboratory

7.8 Sample Rejection Criteria

While every effort is made to minimise rejection of samples, however some samples will be deemed unsuitable for analysis or will yield inaccurate results. These include:

- Unlabelled or incorrectly labelled samples.
- Cancelled orders on PERL for all reproducible samples, essential non-reproducible samples will require relabelling by the requesting ward.
- Incorrect sample type or incorrect additive used in the case of 24 hr urines.
  All 24 Urines or timed urine collections must be checked for proper container suitability i.e. plain container or acid container.
- Inadequate sample volumes.
- Grossly haemolysed samples. Depending on the degree of haemolysis these samples may be unsuitable for analysis and may need to be repeated. In grossly haemolysed samples the following assays should not be reported K, AST, ALT, ALP, GGT, LDH, Iron, Troponin and in some cases phosphate depending on the severity of the haemolysis. Grossly Lipaemic samples may give abnormal reactions for some assays. AST and ALT are the most commonly affected and may not be reported. In more severely-affected samples most assays will be unacceptable and samples should be repeated.
- Contaminated Samples due to incorrect order of draw. If an EDTA sample is taken before the Biochemistry it can affect the Potassium and Calcium measurement.
- Samples taken from an arm with an infusion or a line may yield falsely elevated or decreased results.
- Sample/ Analytes that may have deteriorated due to a prolonged transit time.

7.8.1 Time between Collection and Analysing

Sample Transport may affect testing. The following factors should be considered:

- Timing: off-site blood drawing, delayed centrifugation, leakage of RBCs.
- Temperature (ABGs and K)
- Light exposure (bilirubin, vitamins, porphyrins)

- Clots, Air bubbles (ABG)
- Gross haemolysis, Icterus, Lipaemia

Assays which may be affected include the following but are not limited to:

- Glucose measurement is affected in serum left unseparated at room temperature for > 1hr. Where this might occur fluoride oxalate tubes should be used. Serum samples greater than one hour should not be used for glucose measurement.
- Samples where intracellular concentrations of an analyte (i.e. K, AST, PHOS, LDH, MG, CK and Iron) may increase as a result if sample is left unseparated should be sent to the laboratory promptly.

If a sample has to be rejected the source is informed and a repeat sample must be taken. If a non-repeatable sample is positively identified by the source, a non-compliant disclaimer form is used and a Non-conformance/Quality Event Form is generated on QRM on PERL.

7.9 Urine Collections

Urine containers are available in the Biochemistry Laboratory. The containers available contain acid or no preservative.

7.10 24 Hour Urine Collection Instructions

7.10.1 Preparation

- Before you begin the collection, you will be given a container. The containers available may contain acid or no preservative.
- Place the barcode ordercoms label on the container. If your container is not labelled properly, it will be rejected in the laboratory and you will need to send a repeat sample.
- Ensure container the start and end date and time of the urine collection are recorded on the container.
- During collection keep the container refrigerated until you bring the sample back to the hospital. If this is not possible keep in a cool dry area.
- Some tests require an acid preservative. These containers will have a red acid preservative danger laboratory el with instructions to keep upright, avoid contact with acid fumes and do not pass urine directly into container. The acid is vital for the test so do not empty the container.
- For collection in the acid container collect urine in a clean receptacle (jug/vessel) and transfer. Pour slowly and carefully into the acid container.

7.10.2 Collection Method: Day 1 on Waking

- Start the 24-hour urine test by emptying your bladder directly into the toilet. The collection begins now. Write the start date and time on the container.
- For the next 24 hours all urine passed (no matter how small) must be collected in the container or by receptacle and transferred carefully to the container. If you do not collect all the urine passed in the 24hr your test result may be inaccurate and you may have to repeat the collection again.
- You may need to use more than one container during the 24-hour period. Only when the first container is full should you collect into the second container.

7.10.3 Collection Method: Day 2 on Waking

- Collect the first urine sample into the container. This is the end of the test.
- Write the date and time the test ended on the container.
- Bring the 24-hour collection to the hospital's specimen reception as soon as possible.
- To prevent leaks, ensure the cap is on tightly and the container is stored upright.
- If travelling a long-distance transport on ice or in a cooler.

Notes

1. Ensure that urine and faeces are passed separately.
2. If the container is full before completion of collection, use a second container with the same preservative, and send both to the laboratory. Label containers 1 of 2, 2 of 2 etc.
3. If any specimen of urine is not collected or accidentally discarded during the collection, discontinue the test and start again.
4. Patients should be cautioned not to urinate directly into a bottle containing acid preservative. Below is a list of the appropriate containers for use for each test:

Test	Plain	HCL	Spot
Amylase	YES		YES
Calcium	YES		YES
Chloride	YES		YES
Creatinine	YES		
Potassium	YES		YES
Protein	YES		YES
Protein Creatinine Ratio			YES
Sodium	YES		YES
Urea	YES		YES

Table 6: List of Appropriate Containers for Use for Each Test

Samples for Creatinine, Urea and Urate (if taken into plain container) and BJP should be sent to the laboratory promptly. The container should be stored in the refrigerator during the collection. For 24-hour specimens record the start time and end time of the collection on the container. If more than one container is used over this period, they should be sent to the laboratory together once the collection is finished.

Urine sodium should be interpreted in the light of serum levels and intake. Urine sodium cannot be meaningfully interpreted in patients on saline infusions.

Note: If sending patient home to complete 24-hour urine collection please refer to WI-BIO-0033 Patient Instructions for 24-hour Urine collections.

7.11 Blood Collection Tubes

7.11.1 Biochemistry Profiles

- **Renal Profile**

Requires 5ml of blood in a serum-gel tube mixed gently.

The profile includes sodium, potassium, chloride, total carbon dioxide, urea, creatinine and eGFR (CKD-EPI 2009). Note that bicarbonate decreases in serum with time and the difference in time between phlebotomy and assay of the sample may cause a drop in total CO_2 of 5 mmol/l or more. For accurate assay, the sample should be delivered promptly to the laboratory. Potassium may be increased in haemolysed samples and EDTA contamination.

Where serum is the sample of choice for clinical chemistry analyses, it may be appropriate to measure potassium in a Lithium Heparin sample in patients with thrombocythaemia, leucocytosis or clinically unexplained hyperkalaemia.

- **Liver Profile**

Requires 5ml of blood in a serum-gel tube mixed gently. The profile includes protein, albumin, bilirubin, alkaline phosphatase, AST, ALT and GGT.

False low albumin results may be caused by aspirin. Elevated values of ALT may be produced by a wide range of drugs, which have hepatoxic side effects. Samples for ALT and AST should

be taken before administration of Sulfasalazine and Sulfapyridine as there may be chemical interference with these analytes. Falsely elevated levels of AST may occur as the result of haemolysis. The Clinical Chemistry report may recommend repeat specimen if sample is haemolysed.

Bilirubin is sensitive to light and thus prompt delivery of the specimen to the laboratory is recommended. Cyanokit (Hydroxcobalamin) may cause falsely low results. Samples containing indocyanine green must not be measured. No significant interference from Immunoglobulins was found up to 28g/L, levels above 60 g/L have the potential to give a greater than 40% positive deviation.

- **Bone Profile**

Requires 5ml of blood in a serum-gel tube, mixed gently.

The profile includes albumin, calcium, phosphate and alkaline phosphatase. Calcium may be decreased in samples contaminated with EDTA. Adjusted calcium will not be reported if Albumin result is below 20.

- **Lipid Profile**

Requires 5ml of blood in a serum-gel tube, taken after a fast of at least 12 hours.

The profile includes cholesterol, triglycerides, HDL-Cholesterol, LDL-cholesterol and Non-HDL Cholesterol.

Optimal target values are taken from the European society of Cardiology (ESC) dyslipidaemia guidelines for low risk cardiovascular disease prevention.

- Cholesterol: <5.0 mmol/L optimal (lower levels are recommended in patients with diabetes, hypertension and cardiovascular disease)
- Triglycerides: <1.7 mmol/L optimal
- HDL Cholesterol: >1.00 mmol/l optimal
- LDL Cholesterol: <3.0 mmol/l optimal
- Non-HDL Cholesterol <3.4 mmol/L optimal

- **Lp(a)**

In line with the European Cardiology Society (ESC) Dyslipidaema guidelines Lp(a) analysis is provided by the Clinical Biochemistry laboratory. The ESC recommendation is for knowledge of a patients Lp(a), at least once in a lifetime.

Our laboratory assay is based on Lp (a) molarity as recommended by European Atherosclerosis Society (EAS).

Clinical decision thresholds are quoted as per EAS guidelines.

Lp(a) < 75 nmol/L (optimal)

Lp(a) 75 - 125 nmol/L (intermediate)

Lp(a) > 125 nmol/L (abnormal)

- **Full Iron Profile**

Requires 5ml of blood in a serum-gel tube mixed gently. This includes Iron, Transferrin and % transferrin saturation (a calculation based on these two assays).

- **Haematinics**

Requires 5ml of blood in a serum-gel tube mixed gently. This includes Ferritin, Folate and Vitamin B12. Mainly used for evaluation of blood cell haematopoiesis.

- **Thyroid Function Tests**

Measure Free Thyroxine (FT4) and Thyroid Stimulating Hormone (TSH) as a combined test of thyroid function assayed on the Roche immunoassay e601 platform. The Roche platform is susceptible to Biotin interference, but newer versions of the tests have reduced this. Patients on high Biotin doses must wait 8 hours following last Biotin administration before TFT testing. The Laboratory can arrange to have discordant results repeated on an alternative platform to rule out suspected assay interference, please contact the Biochemistry laboratory directly to arrange this.

As many drugs and treatments affect TFT details of all drugs or other treatment must be provided in order for the Laboratory to initiate further tests as appropriate. Please indicate if the patient is on thyroid replacement therapy when ordering on PERL in the "reason for

exam" section of the order. Autoantibodies to thyroid hormones can interfere with the assay.

- **Creatinine Clearance**

Requires both 5ml blood in a serum-gel tube mixed gently and a 24-hour urine collection (no preservative needed). It is IMPORTANT to take the blood during the period of the urine collection and to send both samples to the laboratory together.

- **Digoxin (includes Lanoxin)**

Required 5ml blood in plain tube (no gel), drawn six hours after the most recent oral dose of digoxin. Used to treat heart failure and atrial fibrillation.

- **Vancomycin/Gentamycin**

Required 5ml blood in plain tube (no gel). Antibiotics used to treat a wide variety of bacterial infections

Refer to consultant Microbiologist for therapeutic range.

- **CRP**

Requires 5ml of blood in a serum-gel mixed well but gently.

An acute phase protein that rises during a general unspecific response to infection and inflammation.

- **Glucose**

Requires 2.5ml blood in fluoride-oxalate tube (yellow laboratory el), mixed well but gently. Serum samples are also acceptable if sent immediately to Laboratory and centrifuged within 1 hour. Also measured in cerebrospinal fluid (CSF).

- **Haemoglobin A1C**

Requires 3ml blood in EDTA tube. Used to assess your average blood glucose concentration over a 2-3 month period.

- **TPSA**

Requires 5ml of blood in a serum-gel mixed well but gently.

Used to aid in the detection and management of Prostate Cancer.

- **CEA**

Requires 5ml of blood in a serum-gel mixed well but gently.

Tested as an aid in the prognosis and management of Cancer patients were changing CEA is observed, which can be seen in many digestive tract cancers.

- **CA153**

Requires 5ml of blood in a serum-gel mixed well but gently.

Primarily used as an aid in management of stage II and III breast cancer patients

- **CA125**

Requires 5ml of blood in a serum-gel mixed well but gently.

Primarily used in monitoring response to treatment in ovarian cancer.

- **NTproBNP**

The natriuretic peptides are used in the evaluation and monitoring of patients with established or suspected heart failure. NTproBNP and BNP have similar clinical utility but results are not interchangeable. There is significant diversity in circulated natriuretic peptides due in part to proBNP processing, glycosylation, complex molecular biology of Heart Failure and lack of harmonisation of immunoassays. NTproBNP is considered a suitable biomarker for monitoring patients receiving NEP inhibitors. NTproBNP rises physiologically with age.

- **PTH**

Requires 3ml blood in EDTA tube. Its secreted by the parathyroid glands in response to decreased extracellular concentrations of ionised calcium. Parathyroid disorders lead to elevated or depressed blood calcium levels.

- **HCG beta**

Requires 5ml of blood in a serum-gel mixed well but gently. Used in the early detection and monitoring of pregnancy. Also can be used in the management of patients with trophoblastic diseases.

- **Vitamin D**

Requires 5ml blood in serum-gel tube. It is essential for bone health and is mainly produced in the skin from exposure to sunlight.

7.12 Blood Gas Analyses

There are five blood gas analysers in the hospital, in ITU, Emergency department, Theatre, St Joseph's ward and Cath Lab. Staff in these areas have been trained to operate these analysers. Samples from all other areas must be hand delivered promptly to the laboratory and must be brought to the attention of a member of staff. The protocol for ABG analysis is as follows:

- A heparinised syringe should contain the patient identifiers i.e. Name, D.O.B and MRN.
- **Any air** in the syringe **must be expelled.**
- The needle must be removed before transport and the syringe capped immediately.

7.12.1 pH and Blood Gases

Requires 3ml arterial blood in air-free heparinised syringe, well mixed.

Reference values: (Arterial)

1. pH: 7.35 to 7.45
2. P_{CO2}: 4.5 to 6.0 kPa
3. P_{O2}: 11.0 to 14.5 kPa
4. Base Excess: -2.3 to + 2.3 mmol/l
5. Std Bicarbonate: 22.4 to 25.8 mmol/l
6. Oxygen Saturation: 95 to 98%

7.12.2 pH and Fluids

Requires a sample of any appropriate body fluid, transferred to a heparinised ABG syringe for testing on the blood gas analyser. Alternatively, it can be tested on fluid with the Siemens multistix test strips.

7.12.3 Lactate

Measured by the ABL90 Flex plus Blood Gas Analyser.

Arterial or Venous blood collected in a blood gas syringe (safe PICO Aspirator).

Can also be measures in a serum sample once centrifuged within 30 minutes.

Samples should be tested within 30 minutes of venepuncture. If longer than 30 minutes but less than 90 minutes samples can still be run but reported with a warning comment.

Reference values (in fasting venous/arterial whole blood): 0.5-2.0 mmol/l

7.13 eGFR

eGFR is a systematic estimation of GFR using creatinine results in adults over 18 years of age.

The CKD-EPI (2009) method for calculation of eGFR (which does not include correction based on race or ethnicity) has replaced the MDRD formula as the preferred method for calculation of eGFR.

The CKD-EPI Creatinine Equation (2009)

The CKD-EPI creatinine equation is based on the same four variables as the MDRD Study equation, but uses a 2-slope spline to model the relationship between estimated GFR and serum creatinine, and a different relationship for age, sex and race. The equation was reported to perform better and with less bias than the MDRD Study equation, especially in patients with higher GFR. This results in reduced misclassification of CKD. As of November 2009, very few clinical laboratories report the estimated GFR using the CKD-EPI creatinine equation. In the future, other GFR estimating equations may outperform CKD-EPI.

The CKD-EPI creatinine equation is:

$$GFR = 141 \times \min(Scr/\kappa, 1)^{\alpha} \times \max(Scr/\kappa, 1)^{-1.209} \times 0.993^{Age} \times 1.018[\text{if female}] \times 1.159[\text{if black}]$$

$\kappa = 0.7$ if female
$\kappa = 0.9$ if male

$\alpha = -0.329$ if female
$\alpha = -0.411$ if male

min = The minimum of Scr/κ or 1
max = The maximum of Scr/κ or 1

Scr = serum creatinine (mg/dL)

Ref: Levey AS, Stevens LA, et al. A New Equation to Estimate Glomerular Filtration Rate. Ann Intern Med. 2009; 150:604-612.

eGFR is not appropriate in patients with rapidly changing renal function in acute kidney injury or in patients receiving dialysis.

7.14 Diabetes Mellitus

The following Table summarises the 2006 & 2011 WHO recommendations for the diagnostic criteria for diabetes and intermediate hyperglycaemia.

	Normal	Impaired Fasting Glucose (Pre-Diabetes)	Impaired Glucose Tolerance	Diabetes Mellitus
Fasting	**3.9-5.6**	5.6-6.9	<7.0	≥ 7.0
	and	and	and	and / or
2 Hour	**<7.8**	<7.8	>7.8 and <11.0	≥ 11.1
				Note: In a symptomatic patient if at least one other abnormal plasma glucose level on another occasion, or HbA1c >48 mmol/mol, then a diagnosis of DM can be made.

Table 7: Diagnostic criteria for diabetes and intermediate hyperglycaemia Adapted from WHO Guidelines 2019.

*** Venous plasma/serum glucose 2–h after ingestion of 75g oral glucose load**

Four diagnostic tests for diabetes are currently recommended, including measurement of fasting plasma glucose; 2-hour (2-h) post-load plasma glucose after a 75 g oral glucose tolerance test (OGTT); HbA1c; and random blood glucose in the presence of signs and symptoms of diabetes. People with fasting plasma glucose values of ≥ 7.0 mmol/L, 2-h post-load plasma glucose ≥ 11.1 mmol/L , HbA1c 48 mmol/mol (≥ 6.5%); or a random blood glucose ≥ 11.1 mmol/L in the presence of signs and symptoms are considered to have diabetes. If elevated values are detected in asymptomatic people, repeat testing, preferably with the same test, is recommended as soon as practicable on a subsequent day to rule in/rule out the diagnosis.

7.14.1 Procedure for Performing a Modified Glucose Tolerance Test

The glucose drink is supplied as a pre-planned pouch with 75g anhydrous glucose in 300ml water.

Ref.: CM-PHL-0002 Glucose Tolerance Test

7.14.1.1 Sampling Procedure

- Prior to starting the fasting patient should eat their normal diet.
- Ensure patient is fasting at least 9 hours but no more than 12 hours, and patient may drink water.
- Take blood samples as per procedure for blood sampling
- Take off first sample & label as fasting, with the time & date of specimen collection.
- Allow patient to drink full contents of Rapilose Oral GTT solution, over 5-10 minutes.
- During the test ensure patient must remain seated in waiting room and refrain from eating, smoking and walking around.
- After exactly 2 hours repeat blood sample to complete the test and label as 2 hour sample, with the time & date of sample collection.

  Ref.: CM-PHL-0001 Blood Sampling in the Phlebotomy Department.

Samples taken in fluoride oxalate tubes and sent to the laboratory for analysis.

7.14.1.2 Short SynACTHen Test

Indication:

- Diagnosis of primary adrenocortical insufficiency.
- Diagnosis of Congenital Adrenal Hyperplasia (CAH). (17 (OH)-progesterone is also measured in this case).

If the basal (i.e. 8am) cortisol is **>450 nmol/**L then adrenal insufficiency is **excluded.** If the basal (i.e. 8am) cortisol is **<80 nmol/L** then adrenal insufficiency exists and there is no need to do a Short Synacthen test in these settings.

Contraindications:

- Pregnancy: It is not advised to perform the Short Synacthen test (SST) during pregnancy. If patient is of child-bearing age, please confirm patient is not pregnant
- Hypersensitivity to Tetracosactide and / or ACTH or to any of the excipients

- Manufacturer states contraindicated in allergic disorders, e.g. asthma. See position statement of Society of Endocrinology Sept 2011
- Avoid in ICU and critically ill patients. Assessment of salivary cortisol may provide an alternative option.

Adverse Effects: Hypersensitivity reactions- tend to be more severe in patients susceptible to allergies and may include injection site reactions, dizziness, nausea, vomiting, utricaria, pruritis, flushing and dyspnoea.

What you need:

- Tetracosactide (SynACTHen®) 250 microgram vial (Order in advance through Pharmacy MPH. Should be stored in fridge until use)
- One I.V. cannula and adhesive (if administering Tetracosactide (Synacthen®) intravenously, a second IV cannula is required)
- NaCl 0.9% 10ml ampoules (IV line flushes)
- Serum sample blood tubes x 3
- Serum blood tubes (white for 17 (OH)-progesterone, if applicable).
- One EDTA tube (pink) for ACTH. Must be taken in cold gel bag and transported to the Clinical Biochemistry Laboratory immediately.
- Syringes

In the unlikely event of an adverse issue, ensure resuscitation equipment is available close by.

Pre-Procedure Notes:

- Discontinuation of OCP/HRT for 6 weeks prior to testing is recommended. If this is not possible discuss with Consultant Clinical Biochemist (Contact through MPH switchboard)
- Prednisolone and hydrocortisone will cross react in the assay and should be stopped for at least 24 hours before testing.

- Enquire about history of asthma or other allergic disorders (see contraindications above and Society of Endocrinology Statement below)
- Enquire if any previous untoward reaction to Synacthen and avoid in these patients.
- There is no requirement for fasting. Ideally, perform the test between 8 and 10 am and no later than 12 midday.
- Take samples for baseline ACTH (ETDA bottle, ***must go to laboratory in cool gel bag immediately***) and basal plasma cortisol (time 0).
- Maintain patency of indwelling IV line by flushing with 2 ml NaCl 0.9% (from NaCl 0.9% ampoules) each time blood sample is taken. Prior to taking blood samples, withdraw 2 ml of blood and discard this blood sample to ensure that the dead space is removed prior to obtaining blood samples.

Procedure:

1. Wash hands.
2. Take samples for basal ACTH and plasma cortisol as outlined above.
3. Administer 250 microgram Tetracosactide (Synacthen®) at time 0 (IM is preferred). If using the IV route, you will need separate IV access to the indwelling cannula for blood draws and flush with 2 ml of NaCl 0.9%.
4. Take further samples for serum Cortisol levels at 30 minutes and 60 minutes post Synacthen injection.
5. If Congenital Adrenal Hyperplasia (CAH) is suspected, request and take blood samples for 17(OH) progesterone at times 0 (baseline), 30 minutes and 60 minutes.

	Std SST	**SST for Dx of CAH**	**Std SST**
Time (minutes)	**Plasma Cortisol**	**17-OH Progesterone (if suspect CAH)**	**ACTH**
0	X	X	X
Inject 250 microgram Tetracosactide (SynACTHen®) IM/IV			

	Std SST	SST for Dx of CAH	Std SST
30	X	X	
60	X	X	
Total number of blood bottles	3 serum tubes (for cortisol), +/- 3 white serum tubes for 17(OH) prog, 1 EDTA tube (for ACTH),		

Table 8: Protocol for Short Synacthen Testing

Interpretation of Results:

- Normal cortisol response following Synacthen stimulation is >450 nmol/L. Interpretation based on stopping OCP/HRT 6weeks before testing
- An abnormal response confirms adrenocortical failure but does not indicate whether the adrenal failure is primary or secondary
- Serum ACTH will be raised in primary adrenocortical insufficiency and low in secondary failure (normal ACTH <46ng/L)
- Interpretation of SST for the investigation of CAH – Refer to Consultant Clinical Biochemist

Assay Methods:

Cortisol is measured by Roche ECLIA method on Cobas which cross reacts as follows:

- 11-deoxycortisol during metyrapone stimulation testing.
- Pregnancy, contraceptives and oestrogen therapy give rise to elevated cortisol concentrations.
- In samples from patients who have been treated with prednisolone, 6-α-Methylprednisolone or prednisone, falsely elevated concentrations of cortisol may be determined.

ACTH is measured by Roche Cobas at MMUH

If you have any queries, please contact the Clinical Biochemistry Laboratory Ph: 8858134 or the Consultant Clinical Biochemist through the Mater Private switchboard.

7.14.1.3 Overnight Dexamethasone Suppression (Screening) Test

Indication:

Used to screen for Cushing's syndrome. Usually performed as an outpatient test.

Contraindications:
None

Note: The oral contraceptive pill (OCP) increases the Cortisol Binding Globulin (CBG) in the circulation. Recommendation: stop OCP for 6 weeks to allow the CBG to return to normal.

Side Effects:

None of note

What you need:

- Dexamethasone tablets 1 mg (Pharmacy)
- One serum gel tube

How to perform test:

1. Request an early morning cortisol and please indicate that this is a sample following administration of dexamethasone when ordering on PERL in the "reason for exam" section of the order. This is essential, if the laboratory is not aware Dexamethasone was administered, they will phone a low cortisol result as urgent
2. Administer 1 mg Dexamethasone orally at 12 midnight.
3. Draw serum Cortisol at 8-9 am the following morning.

Interpretation of Results:

Normal response: Plasma Cortisol should suppress to <50 nmol/L. Sensitivity 98-100%.

Abnormal Response: Plasma Cortisol does not suppress

False positives (i.e. failure to suppress) may occur in:

Patients on enzyme inducing drugs may rapidly metabolise Dexamethasone, e.g. Carbamezepine, Phenytoin, Phenobarbitone, Primidone, Rifampicin, Alcohol

Oestrogens (pregnancy, OCP), hormone replacement therapy (HRT) and Mitotane may induce Cortisol Binding Globulin and increase total Cortisol levels

Patients undergoing dialysis due to rapid clearance of dexamethasone.

False negatives (i.e. suppression) may occur in:

Patients with chronic renal and liver failure due to a failure to clear dexamethasone

Cortisol not suppressed - consider:

Cushing's syndrome (further investigations required)

Non-compliance with oral Dexamethasone

Stress during the night

Increases in Cortisol Binding Globulin

Patient taking anti-convulsant drugs or other enzyme inducing agents

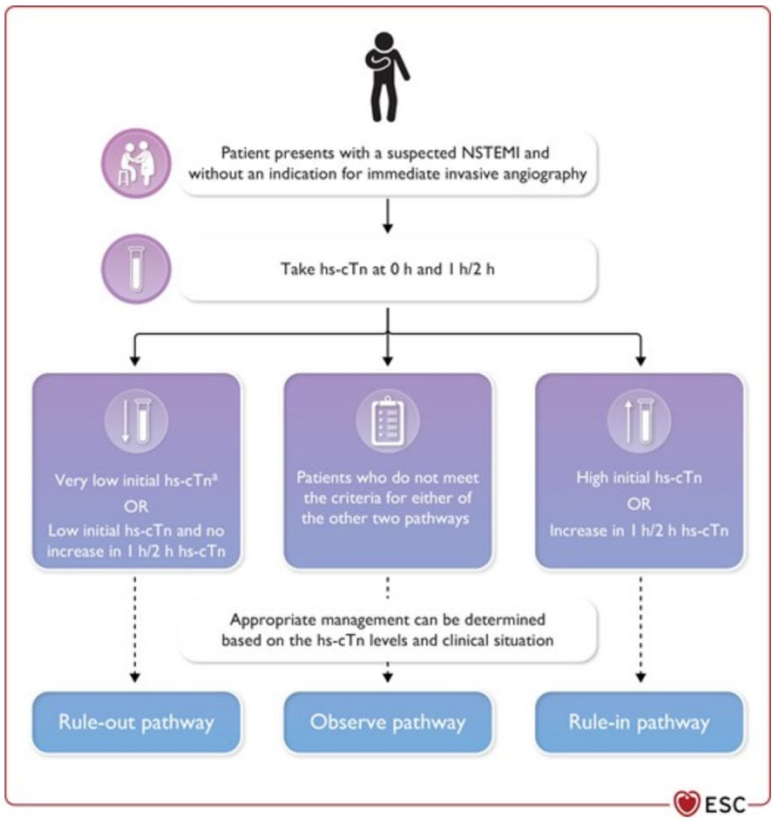
Severe depression

Obesity

7.15 Cardiac Biomarker High Sensitive Cardiac Troponin T (hs-cTnT)

After excluding clinical and ECG signs suggestive of STEMI hs-cTnT is the biomarkers of choice in the diagnosis, risk stratification, and management of patients with suspected acute coronary syndrome (ACS). The goal of testing is to stratify patients requiring reperfusion therapy as soon as possible. The World Health Organization (WHO) criteria for defining AMI are the presence of two of the following three elements: unequivocal ECG changes, unequivocal serum cardiac enzyme changes, and prolonged chest pain.

Recommend to measure hs-cTn on presentation (hs-cTnT Laboratory TAT =75 minutes) Serial hs-cTnT should be measured at 0h/1hr and/or 0h/2hr to rule in/rule out NSTEMI. The 1 hour sample may be sent to the clinical Chemistry laboratory before the result of the initial sample is reported.



Reference: (ESC AMI Guidelines 2023, Prof Robert Byrne *et al*)

Although hs-cTnT is highly specific for myocardial injury, there are many mechanisms and disease states other than coronary heart disease lead to myocardial injury with small increases in hs-cTnT found in both acute and chronic illness (e.g. septicaemia, chronic renal disease, heart failure, etc). It is therefore important the test is **only requested in patients with presentation suggestive of acute coronary symptoms** and that it is not requested as part of a routine screen.

7.16 Clinical and Biochemical Evaluation of a Patient with Potential Secondary Hypertension

This clinical and biochemical guideline is designed to outline the investigations of patients with hypertension for primary aldosteronism and phaeochromocytoma

Primary aldosteronism (PA) is usually diagnosed in patients aged between 20 and 60 years

of age. The prevalence is estimated to be ~ 5% in patients with hypertension. Aldosterone-producing adenoma (APA) and bilateral idiopathic hyperaldosteronism are the commonest subtypes of PA. Hypokaleamia is present in less than 30% of patients.

Phaeochromocytoma/paraganglioma (PPLGs) are rare neuroendocrine tumours arising from adrenal and extra-adrenal chromaffin cells and are generally surgically curable. It is the unregulated secretion of catecholamines that is largely responsible for the hypertension and symptomatology.

A first-line secondary hypertension work-up generally includes clinical and biochemical assessment. Clinical assessment includes detailed BP studies, full cardiac evaluation, weight and metabolic assessment. Obstructive sleep apnoea should be noted and if present should be investigated.

Biochemical investigations include assessments of renal, liver, bone, glucose metabolism, including HbA1c, thyroid function and specialist testing as indicated by clinical symptomatology.

Patient Assessment

Who to test

Patients with early onset hypertension (< 30 years of age), in the absence of hypertension risk factors, such as obesity, metabolic syndrome, familial history)

Those with resistant hypertension

Those with sudden deterioration in BP control

Hypertensive crisis

Adrenal "incidentaloma" with hypertension

Primary aldosteronism (PA) investigations (Pre-analytical)

Aldosterone, Renin and Aldosterone:Renin ratio (ARR) are screening tests and confirmatory testing is advised if results are abnormal or equivocal.

Patient Preparation

No need to fast.

Best practice is to **WITHDRAW** agents that **MARKEDLY** affect ARR as per below;

Anti-Hypertensive Therapies			
Volume management	Loop diuretics (K^+-wasting diuretics)	furosemide	stop 4wk prior to ARR, SIT, AVS
	Thiazide diuretics	bendroflumethazide	
	K^+-sparing diuretics (incl aldo antagonists)	spironolactone, amiloride, triameterene, eplerenone	stop 4wk prior to ARR, SIT, AVS
RAAS agents	ACE inhibitors	captopril, ramipril	stop 2 weeks prior to ARR, SIT, AVS
	Angiotensin II receptor blockers (ARBs)	isostartan	
	Renin inhibitors	aliskiren	
Direct cardiac blockers	β-blockers	metoprolol, nebivolol, bisoprolol	stop 2wk prior to ARR, SIT, AVS
	non-dihydropyridine Ca^{++} channel blockers (selective for myocardium)	verapamil*	
Vasodilators	dihydropyridine Ca^{++} channel blockers (selective for vascular smooth muscle)	amlodipine, nifedipine, lercanidipine	stop 2wk prior to ARR, SIT, AVS
	α1 adrenergic antagonists	doxazosin*	

*Suitable for temporary management of HTN in patients undergoing ARR, SIT and AVS. All others likely to alter renin and aldosterone levels and confound results.

MUST correct severe hypokalaemia (< 3.0 mmol/L) first, as hypokalaemia will reduce aldosterone secretion.

Patient should be ambulatory / upright (sitting, standing or walking) for at least 2 hours prior to the test, however samples best taken between 07:00 – 09:00 hrs during the diurnal peak of aldosterone secretion, then seated for 15 minutes.

Ensure NORMAL hydration and ADEQUATE salt intake – not restriction.

Drug (minimal effect on ARR)	**Class**
Doxazosin e.g. Cardura XL (doxazosin prolonged release) 4 mg OD to max dose 8 mg OD e.g. Cardura (doxazosin) 16 mg OD max dose	Alpha-adrenergic blocker
Hydralazine (unlicensed) e.g. Hydralazine 25 mg BD to max dose 100	Vasodilator

Drug (minimal effect on ARR)	Class
mg BD (greater doses may provoke lupus-like reaction	
Prazosin hydrochloride (not commonly used) e.g. Minipress	Alpha-adrenergic blocker
Terazosin	
Verapamil slow release e.g. Isoptin SR 120 mg OD to max dose 240 mg BD	Non-dihydropyridine calcium antagonist

Table 9: Drugs that have minimal effects on ARR and can be used to control hypertension during screening and confirmation tests for PA.

Drug	Effect	Effect on ARR
ACEI / Angiotensin II receptor antagonist (ARB) e.g. ramipril, losartan	↑renin ↓aldosterone	↓ (FN)
Advancing age	↓↓renin ↓aldosterone	↑ (FP)
Central alpha-2 agonists e.g. clonidine, α-methyldopa	↓↓renin ↓aldosterone	↑ (FP)
Dihydropyridine calcium channel blockers e.g. amlodipine, nifedipine	↑renin ↓aldosterone (acutely) ? No effect long term	↓ (FN)
Hypokalaemia	↑renin ↓aldosterone	↓ (FN)
K+ sparing diuretics e.g. amiloride	↑↑renin ↑aldosterone	↓ (FN)
K+ wasting diuretics e.g. furosemide	↑↑renin ↑aldosterone	↓ (FN)

Drug	Effect	Effect on ARR
Malignant hypertension	↑↑renin ↑aldosterone	↓ (FN)
Mineralocorticoid receptor antagonists (K+ sparing diuretics) e.g. spironolactone, eplerenone Stop 6 weeks	↑↑renin ↑aldosterone (variable effect)	↓ (FN)
NSAIDs e.g. diclofenac	↓↓renin ↓aldosterone	↑ (FP)
Oestrogen-containing oral contraceptives and HRT	↓ DRC and causes false positive ARR , ↑aldosterone	↑ (FP)
Potassium loading	↓renin ↑aldosterone	↑ (FP)
Pregnancy	↑↑renin ↑aldosterone	↓ (FN)
Pseudohypoaldosteronism type 2	↓renin – aldosterone	↑ (FP)
Renal dysfunction	↓renin ↑aldosterone	↑ (FP)
Renin inhibitors Interferes with the catalytic action of renin & prevents conversion of angiotensin to angiotensin 1 Effect depends on how renin is measured	↑↓ renin* ↓aldosterone * renin inhibitors raise DRC (direct renin concentration) ↑ renin* ↓aldosterone * renin inhibitors lower PRA (plasma renin activity) ↓ renin* ↓aldosterone	DRC ↓ (FN) PRA ↑ (FP)
Renovascular hypertension	↑↑renin ↑aldosterone	↓ (FN)
Sodium loaded	↓↓ renin ↓aldosterone	↑ (FP)
Sodium restricted	↑↑ renin ↑aldosterone	↓ (FN)
SSRIs e.g. sertraline, escitalopram	↑↑renin ↑aldosterone	↓ (FN)
βeta-blockers e.g. metoprolol	↓↓renin ↓aldosterone	↑ (FP)

Table 10: Factors that may affect ARR and thus lead to false positive (FP) or false negative (FN) results.

Performing Test (Aldosterone And Renin) (note for Phlebotomy)

Sit patient quietly for 15 minutes prior to venepuncture.

Take a blood sample: one EDTA plasma tube for **BOTH** aldosterone and renin. Send sample **URGENTLY** to laboratory (within half an hour).

Note: **DO NOT USE ICE** for renin samples: ice will cause cryoactivation (conversion of prorenin into renin), giving a falsely high apparent renin activity.

Take a serum sample for Sodium (Na^+) and Potassium (K^+)

Interpretation of Results

Samples for aldosterone and renin are currently sent to Imperial Trust (Charing Cross Hospital)

Analyses of aldosterone and renin are performed by liquid chromatography tandem mass spectrometry methods.

(Turnaround time is 2-3 weeks)

TEST (CHARING CROSS HOSPITAL)	REFERENCE RANGES
Aldosterone (pmol/L)	90 – 700 pmol/L
Plasma Renin Activity (PRA) (nmol/L/hr)	0.5 – 3.5 nmol/L/hr
Aldosterone Renin Ratio (ARR)	< 680: Primary Hyperaldosteronism unlikely > 850: Primary Hyperaldosteronism possible, investigate further > 1700: Primary Hyperaldosteronism very likely

The presence of an elevated Aldosterone Concentration > 400 pmol/L occurring together with a positive ARR increases the sensitivity and specificity to about 90%.

Normal or high renin excludes the diagnosis of PA in almost all cases. Consider secondary hyperaldosteronism with high renin.

A suppressed renin with normal aldosterone level may be pathological.

Interpretative comments are provided on reports.

If you wish to screen a patient who is taking anti-hypertensive medications, please inform the laboratory and results can be interpreted with respect to the specific medications.

Interpretation of Patients Results Who Remain On Anti-Hypertensive Medications

Please document all anti-hypertensive, diuretic and NSAID medications that a patient is receiving on PERL.

It is important to note that anti-hypertensive medications can potentially cause false-negative results, no medication can cause fasle positive results when a cut-off for aldosterone is used.

Calcium channel blockers and α1-adrenergic receptor blockers, potassium-sparing diuretics (amiloride and triamterene) do not affect the diagnostic accuracy in most cases.

Interpretation of results in patients receiving ACEi and ARBs;

ACEi and ARBs have the potential to elevate PRA in patients with mild PA

A PRA level ≥0.5 nmol/L/hr or a PRC that is not suppressed in a patient taking an ACE inhibitor or ARB does not exclude the diagnosis of PA

A PRA level <0.5 nmol/L/hr or a PRC below the reference range in a patient taking an ACE inhibitor or ARB is diagnostic of low-renin hypertension and possible PA

Interpretation of results in patients receiving MRAs;

MRAs (spironolactone and eplerenone) prevent aldosterone from activating the receptor, resulting sequentially in sodium loss, a decrease in plasma volume and an elevation in renin which will reduce the utility of the ARR

If PRA (or Plasma Renin concentration (PRC)) is not suppressed in a patient treated with an MRA, then no further PA-related testing can be performed and the MRA should be discontinued for 6 weeks before re-testing. However, if the patient is hypokalaemic despite treatment with MRA, then the mineralocorticoid receptors are not fully blocked and PRA (or PRC) should be suppressed in such a patient with PA

In addition, most patients with PA who are treated with mineralocorticoid receptor antagonists are given sub-therapeutic doses. Thus, PAC and PRA should be measured in patients treated with MRA, and if PRA is suppressed, these medications are not interfering Thus, if PRA is suppressed, case-detection testing, confirmatory testing, and adrenal vein sampling (AVS) can be performed without discontinuing the mineralocorticoid receptor antagonists

Phaeochromocytoma/paraganglioma (PPGLs) investigations (Pre-analytical)

Who to test

Patients with hypertension (particularly paroxysmal hypertension)

Patients who present with palpitations, headaches and hyperhidrosis

Those with resistant hypertension

Those with sudden deterioration in BP control

Hypertensive crisis

Adrenal "incidentaloma" with hypertension

Plasma metanephrines have been shown to be superior over other tests in the diagnosis of PPGLs.

Patient preparation and sampling (note for phlebotomy)

Patients should avoid caffeine and smoking for 12 hours (overnight) prior to testing. Fasting is advised if 3-methoxytyramine (dopamine metabolite) is being assessed. If a patient has not fasted and has had caffeine (or nicotine) please proceed with taking the samples and note when ordering in the clinical details field called "reason for exam".

Because some medications only increase the likelihood of false-positive results their withdrawal prior to testing is not necessary but should be discussed if unexpected elevated results are found. It is necessary to list the current medications the patient is on when ordering on PERL in the "reason for exam" section of the order. This is required for the interpretation of results.

Patient should be seated for 15 minutes prior to venepuncture.

Plasma metanephrines taken into EDTA blood tube and placed **ON ICE** or brought directly to the laboratory given to the medical scientist to be separated.

Plasma metanephrines, normetanephrine, metanephrine and 3-methoxytyramine are performed using liquid chromatography with tandem mass spectrometry (LC-MS/MS) at the Clinical Biochemistry Laboratory, Mater University Hospital.

In certain circumstances urine metanephrines may be tested but plasma metanephrines are superior.

Urine metanephrines (24-hour collection) are currently analysed at the Clinical Biochemistry Dept., RVI, Newcastle-on-Tyne, UK.

There is no additional role in the measurement of plasma or urine catecholamines in evaluating an adult with hypertension and requests for catecholamines will be analysed for metanephrines.

Interpretation of Plasma Metanephrine Results

Plasma methanephrines have a sensitivity of (99%) and specificity of (89%) in the diagnosis of phaeochromocytoma.

Plasma reference interval (seated)

Metanephrine: 61 – 377 pmol/L

Normetanephrine: 182 – 867 pmol/L

3-Methoxytyramine (3-MT): < 185 pmol/L

Note: The MPN and MMUH reference range is established in seated patients as supine generally impractical for phlebotomy.

It was difficult to get healthy older subjects for reference range studies and the upper reference limit may be higher in older age groups.

Medications and Dietary Interferences

The most troublesome causes of false-positives results are from medications that block neuronal uptake of catecholamines, including TCAs and related drugs used to treat depression, neuropathic pain and other conditions.

The following drug classes may cause false-positive results through pharmacophysiological effects on plasma metanephrine assessment.

Drug	***Examples***
TCAs	Amitriptyline, clomipramine, dosulepin
SSRIs	Citalopram, fluoxetine, sertraline
Serotonin/Norad reuptake inhibitors	Venlafaxine, duloxetine
Monoamine oxidase inhibitors	Isocarboxazid, phenelzine, selegiline
α-adrenergic receptor blockers	Phenoxybenzamine, doxazosin, indoramin
Stimulant/Sympathomimetics	Amphetamine, cocaine, nicotine, caffeine

Major physical stress can also increase metanephrines.

Analytical Interferences

Although analytical interferences are minimised when LC-MS/MS is the technology utilised

to measure plasma (and urine) metanephrines, there is evidence of interference from the vasopressor midodrine with this method.

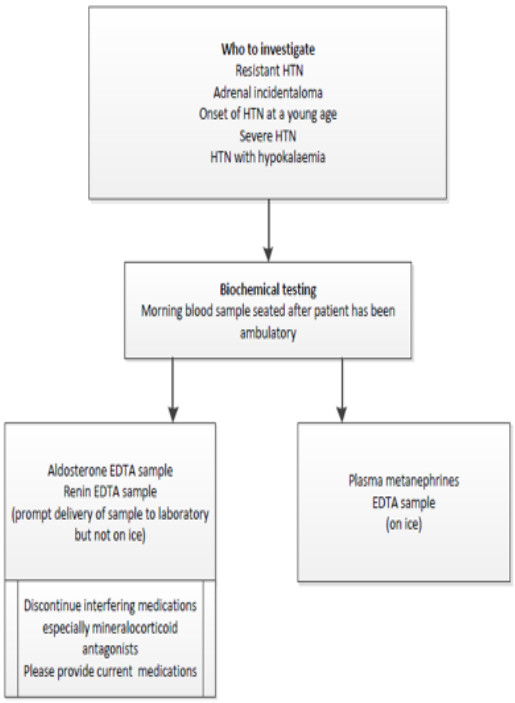
Interpretation of Results

Elevated results should be interpreted with knowledge of a patient's medications.

The most common causes of false-positive results for measurement of plasma metanephrines is associated with sympathoadrenal activation, this can occur when blood sampling is performed when the patient is seated rather than supine.

Where it is not feasible to investigate all patients in a supine position, those with unexplained elevated metanephrine results should have blood drawn after an overnight fast and following 30 minutes of supine rest. Studies have shown that testing in supine position reduces the false positive rate from 18.3% to 3.3%.

If you have received results that are above the upper reference interval and you wish to discuss medication effects on results or you wish to repeat the testing in a supine patient, please contact the Consultant Clinical Biochemist. Please note that reference intervals for supine testing are different to seated reference intervals and we must be aware of this for appropriate interpretation.



Protocol devised by Professor Maria Fitzgibbon, Consultant Clinical Biochemist and Dr Roger Byrne, Consultant Cardiologist, Mater Private Network

References

Young W F Diagnosis and treatment of primary aldosteronism: practical and clinical perspectives Journal of Internal Medicine 285; 2019, 126-148 2019

Eisenhofer G and M Peitzsch Laboratory evaluation of Phaeochromocytoma and Paraganglioma Clinical Chemistry 2014, 1486-1499

International Society of Hypertension Global Hypertension Practice Guidelines 2020

ESC/ESH Clinical Practice Guidelines for the Management of Arterial Hypertension 2018

7.17 Interfering Substances

Many tests are subject to interference. This may be biological, where the offending substance alters the true concentration within the body, or analytical, where the method is

not specific. The report will outline the more common interfering substances such as haemolysis, Icterus (bilirubin interference) and lipaemia. Depending on the degree of interference, some assays may not be reportable.

Factors in performing venepuncture, which may account for haemolysis include:

- Using a needle with a small diameter.
- Using a small needle with a large vacutainer tube.
- Using an improperly attached needle and syringe so that frothing occurs as the blood enters the syringe.
- Pulling the plunger of a syringe back too quickly.
- Shaking or vigorous mixing of blood collection tubes.
- Forcing blood from a syringe into a blood collection tube, especially through a needle.
- Failure to allow the blood to run down the side of the tube when using a syringe to fill the tube.
- Failure to allow alcohol swab to dry.
- Drawing from site of haematoma.
- Very slow flow into tube.
- Drawing blood from indwelling line.

7.18 Critical Alert Values

All critical results must be phoned immediately when results become available so that intervention may take place promptly and must be logged on the PERL including name of attending nurse/doctor. It is the aim of the laboratory to ensure these critical / alert values reach the clinical team within 30 minutes of the result being reported where possible. The process for phone a critical result is as follows:

1. Phone the ward mobile phone/requesting source with the critical result within 30 minutes.
2. If uncontactable, repeat process two further times.

3. If no response from the ward mobile phone/requesting source, contact the CNM over the area (SIL-NUR-035).
4. Out of hours, if the CNM is uncontactable, phone the clinical site manager (SIL-NUR-035) and raise a non-conformance against the ward on QRM on PERL.

Always record the following details in the PERL phone log when critical /alert values are notified to the ward:

1. Name of staff member phoning the result
2. Name of member of staff notified of critical result
3. Time phoned to the ward

In the event that the medical scientist is unable to make contact with the requesting clinician or clinical personnel responsible for patient, for example in an outpatient capacity, the medical scientist must contact the Consultant Biochemist on-duty.

For the most up to date Critical Alert Values, please see the home page of the Hospital Intranet / Laboratory Handbook & Critical Alert Values. If you are unable to access the intranet, please contact the relevant department.

Ref.: LS-BIO-0020 Clinical Authorisation and Reporting of Results in the Biochemistry Department, WI-BIO-0005 Biochemistry Critical Values and LS-GEN-0005 Reporting of Results

7.18.1 Uncertainty of Measurement

Many factors contribute to the uncertainty of results produced by automated instruments. Factors that contribute to the uncertainty would include, but are not limited to:

(1) **Pre-analytical factors:** for example phlebotomy technique, sample transportation and sample storage prior to analysis. While these need to be considered, they are variables that are beyond the scope of this procedure and will not be discussed further.

(2) **Analytical factors:** uncertainty of measurement due to variables in the reagents, calibrators, controls and sample handling (pipetting, tubing, sample cuvettes) by the instrument. These variables are the subject of this procedure.

The Uncertainty of Measurement is available for each analyte on request from the Biochemistry Department.

Please note that patients should avoid taking any Biotin supplements for 24 hours prior to testing as Biotin can cause assay immunoassay interferences on Roche instruments.

Contact Details

Clinical Biochemistry Laboratory Phone: 01885 8134

Gerry Cox, Chief Medical Scientist, Email: gerry.cox@materprivate.ie

Dr Paula O'Shea, Consultant Clinical Biochemist

Email: Paula O'Shea <PaulaOShea@mater.ie>

Dr Graham Lee, Consultant Clinical Biochemist/UCD Associate Clinical Professor.

Email: Graham.Lee@materprivate.ie

8. IMMUNOLOGY/SEROLOGY

8.1 General

Immunological tests can be graded according to their usefulness in patient care. Some tests are essential for diagnosis and monitoring of disease activity, and some are useful for routine investigation. The following table contains a repertoire of tests analysed in the immunology department.

Serology testing is carried out within the Immunology department -see section 5.4 1 for repertoire of serology tests.

8.2 Repertoire of Tests - Immunology

TEST	ORDER CODE	SPECIMEN VOLUME	SPECIAL PRECAUTIONS	TAT	REFERENCE RANGES	Source
Cryoglobulin	CRYOS	2 x 7.5ML clotted 1 x 2.7ml EDTA	Contact phlebotomist regarding special requirements. Samples can be received in laboratory Monday -Thursday before 12pm.	1 Week	Positive/Negative	N/A
Immunoglobulins	IMG	7.5ml clotted	Spin and store at 2-8°C	1 Week	IgG 6.0-16.0g/L IgA 0.85-4.99 g/L IgM 0.35-2.42g/L	The Binding Site
Protein Electrophoresis	SPEP	7.5 ml clotted	Spin, separate and store at 2-8°C	1 Week	Total Protein 64-82 g/L Albumin 35-50 g/L Alpha-1 1-2 g/L Alpha-2 6-9 g/L	Sebia

TEST	ORDER CODE	SPECIMEN VOLUME	SPECIAL PRECAUTIONS	TAT	REFERENCE RANGES	Source
					Beta-1 4-7 g/L Beta-2 2-5 g/L Gammaglobulin 6-13 g/L Interpretative comment	
Immunofixation of serum.	IEF	7.5 ml clotted	Spin, separate and store at 2-8°C	2 Weeks	Interpretative comment	N/A
Bence Jones Protein -24 Hour sample	BJP24	24 hr urine collection (Plain Container)	Urines should be fresh for analysis and stored at 2-8°C. A 24-hour collection is preferable. An early morning urine specimen may be analysed. However, if Bence Jones protein is present it cannot be quantified.	1 Week	g/24 Hours	N/A
Bence Jones Protein – Spot sample	BJP.SPOT	Spot Urine Sample		1 Week	Positive/Negative	N/A
Serum Free Light Chains	SFLC	7.5ml clotted	Spin, and store at 2-8°C	1 week	Kappa: 3.3-19.40 mg/L Lambda: 5.71-26.30 mg/L	The Binding Site

TEST	ORDER CODE	SPECIMEN VOLUME	SPECIAL PRECAUTIONS	TAT	REFERENCE RANGES	Source
					K/L Ratio: 0.26-1.65	
Beta-2 Microglobulin	B2M	7.5ml clotted	Spin, and store at 2-8°C	1 week	0.8-2.34 mg/L	The Binding Site
Autoantibody Tests (Phadia Analyser)	TTG ANCA GBM CTD ENA DNA M2 PCA INTF	4.9ml clotted	Spin, and store at 2-8°C	1 week	Positive/Negative	Phadia

Table 11: Repertoire of Immunology Tests

8.2.1 Specific Proteins

8.2.1.1 Immunoglobulin Levels

Immunoglobulins are formed as a humoral response to contact of the immune system with antigens. The initial reaction is production of IgM antibodies, followed later by IgG and IgA antibodies. Quantitative determination of immunoglobulins can provide important information on the humoral immune system. All requests for immunoglobulin levels automatically include protein electrophoresis analysis. One exception is oncology patients where protein electrophoresis has been performed on the initial specimen and the oncology clinician requires only the immunoglobulin levels on subsequent specimens.

8.2.1.2 Protein Electrophoresis

Serum or urine may be screened for protein abnormalities using protein electrophoresis. Serum can be separated into well-defined fractions by electrophoresis, stained and the stained electrophoretic separations can be evaluated visually for pattern abnormalities. Urine specimens can be run for the detection of Bence Jones proteins. Combined with the quantification of serum total protein and immunoglobulin levels, protein electrophoresis is an essential aid to the diagnosis and therapeutic follow-up of acute diseases especially the malignant monoclonal gammopathies and immunodeficiencies. All requests for serum protein electrophoresis automatically include immunoglobulin level quantitation.

8.2.1.3 Immunofixation (Serum & Urine)

Immunofixation is the procedure for typing paraproteins according to their heavy and/or light chains. If a paraprotein is detected following protein electrophoresis, the laboratory proceeds with typing and quantitation. There is no indication for the routine request for immunofixation.

8.2.1.4 Serum Free Light Chains

Measurement of serum free light chains aids in the diagnosis and monitoring of multiple Myeloma, Lymphocytic neoplasms, Waldenstroms macroglobulinaema, AL amyloidosis, light chain deposition disease and connective tissue disease.

8.2.1.5 Beta 2 Microglobulin

Beta 2 Microglobulin is a protein found on the surface of most nucleated cells. It is eliminated through the kidneys. Normally only trace amounts are excreted in the urine; however this is markedly increased in tubule-interstitial disease. Raised levels of Beta 2 Microglobulin are associated with renal disease and rheumatoid arthritis, Systemic Lupus Erythematosus, malignant lymphoma and myeloma.

8.2.2 Autoantibody Screening

8.2.2.1 Coeliac Screening

Tissue transglutaminase has been identified as the major autoantigen in coeliac disease. IgA antibodies against tTG are highly disease specific serological markers for coeliac disease and dermatitis herpetiformis. Samples are screened for Anti-tTG and referred for Endomysial antibodies if positive

8.2.2.2 ANCA/GBM (Vasculitis) Screening

If autoimmune vasculitis is suspected, samples can be screened for anti neutrophil cytoplasmic antibodies (ANCA) which involves testing for antibodies to Proteinase 3 (PR3)/ Myeloperoxidase (MPO) and if required, antibodies to glomerular basement membrane (GBM).

- Antibodies to PR3 are highly sensitive and specific for granulomatosis with polangiitis (GPA/ Wegener's granulomatosis). Antibodies to PR3 can also be an indicator of microscopic polyangiitis (MPA) and eosinophilic granulomatosis with polyangiitis (EGPA/ Churg-Strauss syndrome). PR3 antibodies may also occur in patients with necrotizing glomerulonephritis (NCGN).
- Antibodies to MPO can be found in patients with NCGN without immune deposits (pauci-immune), NCGN associated with systemic vasculitis, either GPA/ Wegener's granulomatosis or MPA and in EGPA/ Churg-Strauss syndrome).
- Antibodies to GBM can be fount in patients with Goodpasture Syndrome, Anti-GBM disease and ANCA associated vasculitis.

8.2.3 Connective Tissue Disease Screening

The determination of antinuclear antibodies (ANA) is of central importance for the clinical diagnosis of connective tissue diseases (CTD), which are systemic inflammatory diseases with a chronic course of disease. Connective tissue diseases exhibit overlapping symptomatic features that render an accurate diagnosis difficult. The CTD, Extractable nuclear antigen (ENA) and double stranded DNA (dsDNA) screens are intended for the in

vitro qualitative measurement of antinuclear IgG antibodies in human serum and plasma as an aid in the clinical diagnosis of CTD's such assystemic lupus erythematosus (SLE), mixed connective tissue disease (MCTD), Sjögren's syndrome, scleroderma and polymyositis/dermatomyositis. Samples are screened using the CTD screen and are referred for an ENA and a dsDNA screen if positive.

8.2.4 Inflammatory Arthritis Screening

Samples from patients with suspected inflammatory arthritis can be screened for Rheumatoid Factor (RhF) and cyclic citrullinated peptide antibodies (Anti-CCP). Both antibodies are an indicator of rheumatoid arthritis and can be used in the diagnosis and prognosis of the disease.

8.2.5 Autoimmune liver antibody screening (Anti-M2)

- Mitochondrial antibodies (Anti-M2) are useful in the diagnosis of Primary Biliary Cirrhosis (PBC)

8.2.6 Parietal Cell/Intrinsic Factor antibodies

Parietal cell and intrinsic factor antibodies (Anti-PCA & Anti-IF) are useful in the diagnosis and prognosis of pernicious anaemia.

8.3 Specimen Stability

8.3.1 Serum Specimen Requirements

Immunology serum specimens are spun and stored at 2-8^{o}C. The exception to this is cryoglobulin testing. For cryoglobulin assay the unclotted specimen should be taken immediately to the laboratory and allowed to clot at 37°C because cryoglobulins may precipitate at ambient temperature and be lost in centrifugation.

Samples are discarded 48 hours after the final report has been issued.

Urine Specimen Requirements:

A morning void is sufficient for the detection of BJP but a 24-hr collection is necessary for quantitation.

8.3.2 24-hour Urine Collection Instructions

Urine containers are available in the Pathology Laboratory.

Accurately timed, complete urine collections are a vital part of many tests. See Table 11 for tests which require 24 hours urine collections.

Obtain a urine container. Choose a convenient time to start the collection usually in the early morning, e.g. 8am. If collecting on a ward, it is convenient to have a routine time for starting all collections. If results are required on the day of completion, specimens must be received in the laboratory by 10am.

Day 1

- 8am
- Ask the patient to empty their bladder completely and discard this specimen. Thereafter collect all urine passed into this container for the next 24 hours.

Day 2

- 8am
- Ask the patient to empty their bladder completely and add this specimen to the collection.
- Collect no more urine.
- For 24-hour specimens, ensure the date and start and finish time of collection is written clearly on the bottle.

Notes

1. Ensure that urine and faeces are passed separately.
2. If the container is full before completion of collection, use a second one and send both to the laboratory. Label containers 1 of 2, 2 of 2 etc.
3. If any specimen of urine is not collected or accidentally discarded during the collection, discontinue the test and start again

4. Patients should be cautioned not to urinate directly into a bottle containing acid preservative. Below is a list of the appropriate containers for use for each test:

The container should be stored in the refrigerator during the collection. If more than one container is used over this period, they should be sent to the laboratory together once the collection is finished.

8.4 Serology

8.4.1 General

Serology tests can be used to diagnose infections by assessing the patient's antibody response to a particular infective agent. The department offers a comprehensive range of serological screening investigations (Syphilis, HIV, Hepatitis A, B and C). The service is for the purposes of screening specimens including pre-dialysis screening, routine dialysis screening, visa applications, insurance purposes, pre-adoption screening, college applications, staff samples etc. The laboratory also offers an urgent 24-hour needle stick injury service (see section 5.5). Consent for Needle stick injury specimens from the patients will be obtained at ward level. Any clinically relevant reactive specimens will be forwarded onto the National Virus Reference Laboratory for confirmatory testing.

8.4.2 Repertoire of Tests

TEST	ORDER CODE	SPECIMEN VOLUME	SPECIAL PRECAUTIONS	TAT	REFERENCE RANGES	Source
HIV Hepatitis Screen Hepatitis A Hepatitis B (HBsAg) Anti-HBc Hepatitis C Syphillis	HIV HEPATITIS HEPA HBSAG HBCAB SYPSCR	7.5 ml clotted	Spin and store at 2-8°C	3 Days	Positive/Not detected	Roche

TEST	ORDER CODE	SPECIMEN VOLUME	SPECIAL PRECAUTIONS	TAT	REFERENCE RANGES	Source
Anti-HBs	HBSAB	7.5 ml clotted	Spin and store at 2-8°C	3 Days	<10 IU/mL: Not Detected (If vaccinated this patient has not responded to vaccination > 10 Iu/mL Positive Adequate Anti-HBs response. No need for further testing)	Roche

Table 12: Repertoire of Serology Tests

8.4.3 Serum Specimen Requirements

Serology serum specimens are spun and stored at 2-8°C. Samples are discarded 48 hours after the final report has been issued. Additional tests can be requested up to 48 hours after the final report has been issued.

8.5 On-Call Service Repertoire in Immunology

The Immunology Laboratory offers an urgent 24-hour service for needle-stick injury **source** specimens. In the event of a needlestick injury with **a known source**, the laboratory must be contacted directly and informed that there is an urgent specimen on the way. The **source** specimens are processed immediately and the Occupational Health Department are informed immediately of any reactive specimens. All other requests (including samples from a needlestick injury with **an unknown source**) can be processed during routine laboratory hours.

8.6 Critical Values in Immunology

For the most up to date Critical Alert Values, please see the home page of the Hospital Intranet / Laboratory Handbook & Critical Alert Values. If you are unable to access the intranet, please contact the relevant department.

9. HAEMATOLOGY

9.1 General Information

The procedures carried out in the Haematology Department broadly fall into the categories of:

(i) Screening a blood specimen for an abnormality

(ii) Making a diagnosis of a blood disorder

(iii) Investigating in detail a patient in which a tentative diagnosis of a particular blood disorder has been made and subsequent treatment is warranted, initiated and to be monitored.

9.2 Test Repertoire

Test	Abbr.	Specimen Type	Turn Around Time	Reference Ranges	Source
Activated Partial Thromboplastin Time	APTT	Na Citrate 9NC 3 ml	2 Hours	25.1-32.9 seconds	Established in laboratory
Activated Partial Thromboplastin Time Ratio	APTTRT	Na Citrate 9NC 3 ml	2 Hours	Reference range 0.8-1.2 (for patients not on anticoagulant).	Established in laboratory
Correction Studies		Na Citrate 9NC 3 ml	½ Day	Reduction of Original Results (secs)	N/A
D Dimers	DD	Na Citrate	2 Hours	<0.50ug/ml	Established in laboratory

Test	Abbr.	Specimen Type	Turn Around Time	Reference Ranges	Source
		9NC 3ml			
Differential		K EDTA 2.7 ml	Same Day	NEUT 6 years 2.00-6.00 x 10^{9}/L Adult 2.00-7.50 x 10^{9}/L LYMP 6 years 5.50-8.50 x 10^{9}/L Adult 1.50-4.00 x 10^{9}/L MONO 6 years 0.70-1.50 x 10^{9}/L Adult 0.20-0.80 x 10^{9}/L EOSI 6 years 0.30-0.80 x 10^{9}/L Adult 0.04-0.40 x 10^{9}/L BASO 0.00-0.10 x 10^{9}L	Dacie and Lewis *Practical Haematology*
Erythrocyte Sedimentation Rate	ESR	Na Citrate 4NC 3.5 mls	2 Hours	0-10 Male 0-20 Female	Established in laboratory
Fibrinogen	FIB	Na Citrate 9NC 3 ml	2 Hours	2.0-4.0 g/l.	Established in laboratory
Full Blood Count	FBC	K EDTA 2.7 ml	1 Hour	WBC 12 years 4.5-13.5 x 10^{9}/L	Dacie and Lewis *Practical*

Test	Abbr.	Specimen Type	Turn Around Time	Reference Ranges	Source
				Adult 4.00-11.00 x 10^{9}/L RBC 12 years 4.00-5.40 x 10^{12}/L Adult (f)3.80-5.80 x 10^{12}/L Adult (m)4.50-6.50 x 10^{12}/L HGB 12 years 11.5-14.5 g/dL Adult (f) 11.5-16.5 g/dL Adult (m) 13.0-18.0 g/dL HCT 12 years 0.37-0.44 x L/L Adult (f) 0.37-0.47 x L/L Adult (m) 0.40-0.54 x L/L MCV 12 years 77.0-91.0 f/L Adult 80.0-100.0 f/L MCH 12 years 24.0-30.0pg Adult 28.0-32.0pg MCHC 32.0-36.0 g/dL RDW 11.0-15.0% PLTS 150-400 x 10^{9}/L	*Haematology*
International Normalised Ratio	INR	Na Citrate 9NC 3 ml	2 Hours	Determined by clinical state	N/A

Test	Abbr.	Specimen Type	Turn Around Time	Reference Ranges	Source
Routine blood film Review	FILM	Blood Film	2 Working Days	N/A	N/A
Haematologist blood film review	CBF	Blood Film	2 Weeks	N/A	N/A
Iron Stain		Bone Marrow Aspirate Slide	Batch of slides stained once weekly	Reduced/Normal/Raised	N/A
Prothrombin Time	PT	Na Citrate 9NC 3 ml	2 Hours	11.4-15.0 seconds	Established in laboratory
Reticulocytes	RETIC	K EDTA 2.7 ml	Same Day	35-132x109/L	Dacie and Lewis *Practical Haematology*

Table 13: Repertoire of Haematology Tests

Malarial Screens and Sickle screens are sent for referral testing to MMUH.

9.3 Sample Volume

It is important that blood tubes, especially those containing preservative for coagulation test, ESR and FBC are filled to the stated capacity. This reduces the risk of insufficiency or interference from a preservative and rejection of sample due to the wrong volume in tube.

9.4 Handling Urgent Specimens

To achieve an overall effective service urgent requests are kept to a minimum and are essentially those necessary for the immediate clinical management of the patient.

Time limits of analysis, while documented are monitored through turnaround times, reflecting actual practice and addressed locally to meet service needs.

In the Haematology department a number of sources are given priority i.e. Day Oncology, Intensive Care Unit, ED, Chest Pain

- The sickle screen and malaria test is treated as urgent and referred to MMUH.

All other specimens will be processed routinely unless

- The test is requested as stat on PERL if urgent and laboratory should be informed.
- Direct contact has been made with the laboratory by the Clinician/ healthcare professional with responsibilities for care of the patient.
- The Clinician/healthcare professional must agree
  - Which tests are necessary
  - The target time for completion
  - Where reports are to be directed, if required.

9.5 Information about Haematology Tests

1. Full Blood Count (FBC), results given for white cell count including differential, red cell counts, haemoglobin, haematocrit (HCT) red cell indices and platelet count.
2. From the results of red cell indices, anaemia can be classified as normochromic, hypochromic, microcytic or macrocytic and further investigations organised.

3. Blood film will be examined if requested with relevant clinical information or if indicated by the FBC. In the presence of a normal FBC, there are few indications for routine film examination e.g. possible infectious mononucleosis.
4. Reticulocyte counts are useful to check for increased red cell production e.g. haemorrhage, haemolysis, haematinic therapy (iron, V. B12 or folic acid) or investigating unexplained anaemia.
5. Eosinophil counts will be determined with the differential and expressed as an absolute number. A variety of conditions can lead to an increased count e.g. hyper-sensitivity states, parasitic infections or skin disease.
6. Erythrocyte sedimentation rate (ESR) is not a reliable test for confirming health or diagnosing disease. It has a role indicating inflammation and following the effects of therapy e.g. giant cell arteritis (GCA). Except in the case of GCA it is not an emergency test.
7. Bone marrow studies – aspirate, trephine smear, sections and karyotype have a major role investigating macrocytosis, leukaemia etc. Unless skilfully performed these procedures can be unnecessarily painful, dangerous and unsuccessful. Spreading of marrow aspirate is difficult. Please arrange with haematology medical staff.
8. Coagulation studies can be confusing if their management is not informed. For the most reliable results, blood must be in the laboratory within one hour of sampling and not taken from heparinised I.V. lines or bungs.
9. PT/INR, APTT, fibrinogen and FBC (for platelet count) are the most frequently used tests for initial screening of haemostasis.
10. D-Dimers are a reliable indicator of thrombosis.
11. INR monitors anticoagulant therapy with Vitamin K antagonists. The INR will also be prolonged with excess heparin anticoagulation, disseminated intravascular coagulation (DIC) and in rare coagulation factor deficiencies e.g. Factor VII.
12. APTT is the most useful measure of heparin therapy. APTT results should be 1.5 to 2.5 times patient's baseline value or the midpoint of the reference range. Prolonged

values in moderate to severe haemophilia, Christmas or Von Willebrand's disease. Rarely DIC or circulating anticoagulants e.g. lupus are found to cause prolonged values.

9.6 Time Limits for Requesting Additional Examinations

TEST/ EXAMINATIONS	TIME LIMIT (FROM ORIGINAL SPECIMEN RECEIVED)
Reticulocyte Count	8 hours
Blood Film	Same day as collection
Correction Studies	4 hours
D-Dimers	8 hours
PT/APTT/INR	4 hours
Fibrinogen	8 hours

Table 14: Time limits for requesting additional tests

9.7 On-Call Service Repertoire in Haematology

The following is the repertoire of tests available in Haematology outside of routine working hours

- FBC
- PT/INR, APTT, Fibrinogen, D Dimers.
- Sickle screens and malaria testing are referred externally to the Mater Misericordiae Hospital, once confirmation of the urgency has been confirmed by the healthcare professional looking after the patient.

Note: All other requests are processed during routine laboratory hours.

9.8 Critical Alert Values

Any test results that are significantly outside the normal reference range may indicate a high risk of life-threatening condition. Clinical personnel responsible for the patient care will be

immediately notified when examination results for critical properties fall within established "critical intervals". This includes results received on specimens sent to referral laboratories.

Critical Result criteria: For the most up to date Critical Alert Values, please see the home page of the Hospital Intranet / Laboratory Handbook & Critical Alert Values. If you are unable to access the intranet, please contact the relevant department.

Ref.: LS-HAEM-0016 The Handling of Specimens in the Haematology Department & WI-HAEM-0001 Haematology Critical Alert Values

In Haematology all requests from Day Oncology, Emergency Department, Chest Pain Clinic and ITU are processed urgently. All requests that are marked urgent are processed immediately.

9.9 Factors that could significantly affect the performance or interpretation of the result

Haemoglobin: it is important to avoid haemolysis either during or after the collection of the blood specimen, otherwise the result is invalid.

Red cell count: there is a moderate fluctuation during the 24 hours of about 4 per cent probably related to exercise meals and fluid intake etc. Strong emotions such as fear cause a temporary increase in the red cell count.

Platelets: pseudothrombocytopenia due to platelet aggregation (clumping) in EDTA blood may be found. This artefact is of no clinical significance, can be identified in the laboratory and resolved by supplying Thromboexact specimen for platelet count only.

While red cell white cell and platelet numbers are stable for at least 24hours in EDTA, progressive morphological changes in a blood film are however inevitable.

Prolonged INR's may be due to relative overdose or increased sensitivity by the patient. This may be a consequence in severe illness, interaction with a potentiating drug, and withdrawal of antagonistic drugs.

10. BLOOD TRANSFUSION

10.1 General Information

The Blood Transfusion Laboratory performs tests to ascertain the blood group of patients and to determine whether patients' plasma contains antibodies to red cell antigens. The presence of these unexpected antibodies needs to be investigated and the antibody or antibodies must be identified. Compatibility testing is carried out in order that suitable blood components are readily available for surgical patients and patients requiring blood component therapy.

10.2 Blood Transfusion Tests

Blood Product	**Specimen Type**	**Specimen Requirements**			**Where available**	**Turnaround Time**
		Additive Required	***Volume Required ml***	***Container Type***		
Red Cells /CMV Neg Irradiated	Blood	EDTA	7.5	Blood Tube	Blood Transfusion laboratory	3 hours
Type and Screen & Second Group	Blood	EDTA	7.5	Blood Tube	None	Same Day (2 hour if requested urgently)
Type and Crossmatch (blood group unknown)	Blood	EDTA	7.5	Blood Tube	None	3hours
Additional request for red cells	Blood	EDTA	7.5	Blood Tube	None	1 hour
Direct Coombs Test	Blood	EDTA	7.5	Blood Tube	None	Same Day

Blood Product	Specimen Type	Specimen Requirements			Where available	Turnaround Time
		Additive Required	***Volume Required ml***	***Container Type***		
Transfusion Reaction Investigation	Blood	EDTA / clotted/serum sample	7.5	Blood Tube / Clotted	See Section 7.12	7 days
Antibody Identification	Blood	EDTA	7.5	Blood Tube	None	4 hours
Red Cell Phenotyping	Blood	EDTA	7.5	Blood Tube	None	4 hours

Table 15: Blood Transfusion Repertoire of Tests

Note: A Blood grouping report is issued in PERL on completion of pre-transfusion testing. Where an antibody(s) have been identified in the patient's plasma and blood may be require for surgery or transfusion, please be aware that additional time will be required for the provision of antigen negative compatible blood.

10.3 Blood Products for Transfusion

*** If the patient has a CMV- Irradiated special requirement units may need to be ordered from the IBTS (delivery time approx. 1 hour)**

****A Type and Screen sample is required if the blood group has not been previously established by the MPN laboratory.**

Blood Product	Specimen Type	Specimen Requirements			Where available	Turnaround Time
		Additive Required	***Volume Required ml***	***Container Type***		
Red Cells /CMV Negative Irradiated*	Blood	EDTA	7.5	Blood Tube	Blood Transfusion Laboratory	3 hours (non-urgent) 1 hour (urgent)

Blood Product	Specimen Type	Specimen Requirements			Where available	Turnaround Time
		Additive Required	***Volume Required ml***	***Container Type***		
Solvent Detergent Plasma (Octaplas)**	Blood	EDTA	7.5	Blood Tube	Blood Transfusion laboratory	45 minutes
Platelets (Pooled, Apheresis or HLA Matched)**	Blood	EDTA	7.5	Blood Tube	Available on request (IBTS)	2 hours
Octaplex	none	none	none	none	Blood Transfusion laboratory	20 mins
Fibrinogen concentrate	none	none	none	none	Blood Transfusion laboratory	20 mins
Recombinant VIIa (Novoseven)	none	none	none	none	Available from Blood Transfusion laboratory on a limited basis for specific patients following consultation with	20 mins

Blood Product	Specimen Type	Specimen Requirements			Where available	Turnaround Time
		Additive Required	***Volume Required ml***	***Container Type***		
					Consultant Haematologist	
Albumin	None	None	None	None	Blood transfusion laboratory	20 mins
Coagulation Factor Concentrates e.g. Wilate=VW factor Advate=Factor VIII	None	None	None	None	Available following consultation with the Consultant Haematologist- ordered in advance	2 – 4 hours

Table 16: Blood products/components available from Blood Transfusion Laboratory

10.4 Description of Blood Components /Products

10.4.1 Red Cells

RCC (red cell concentrate) are supplied by the IBTS. Stock of the various blood groups (A, B, O, AB) is held refrigerated in the Blood Transfusion Laboratory. RCCs have a shelf life of 35 days. Minimum stock levels have been defined; these ensure an adequate supply of blood for routine & emergency use, while at the same time minimise wastage due to outdating. Note: CMV negative, irradiated red cells are stocked on a limited basis, and can be obtained from the IBTS on a patient requirement basis.

10.4.2 Platelets

Due to their relative short shelf life (5 days) & challenges surrounding supply these are only ordered from the IBTS as required. To ensure viability they are stored at 22°C on an agitator in the Blood Transfusion laboratory. Once removed from the laboratory, platelets must be transfused immediately.

10.4.3 Octaplas/™

Octaplas is a pooled human plasma product, containing plasma proteins. A stock is held continuously at MPH. This product is frozen & has a long shelf life (2-4 years), however once thawed must be administered within 4 day when stored at 4C.

10.4.4 Human Albumin

The Blood Transfusion Laboratory holds a constant supply of 5% & 20% albumin. It is stored in the laboratory until ready for infusion.

10.4.5 Fibrinogen

Fibrinogen concentrate is made from pooled plasma, which is available in 1gram amounts. Stock is held in the Blood Transfusion Laboratory, and when requested is available within 15 minutes.

10.4.6 Prothrombin Complex Concentrate (Octaplex™)

Octaplex is a coagulation factor concentrate, specifically Prothrombin complex concentrate. A limited stock is held in Blood Transfusion laboratory. Consultation with a Consultant Haematologist is required prior to administration of this product.

10.4.7 Recombinant Coagulation Factor (Novoseven ™)

Novoseven is a recombinant coagulation factor, specifically factor VIIa. It is available in 2 mg solution for reconstitution & is available from the laboratory on a limited basis for specific patients. Consultation with a Consultant Haematologist is required prior to administration of this product.

10.4.8 Coagulation Factor Concentrates

Wilate (Von-Willibrand factor), Advate (factor VIII). Such products are available only following consultation with Consultant Haematologist and on a communicated patient plan only. The Blood Transfusion Department needs at least four weeks' notice to ensure that the coagulation factors can be sourced from the supplier.

Further information regarding indication for use, dosage and specific administration guidelines are available on the MPH intranet, specifically policy entitled NUR-HAE-001.

10.4.9 Referrals

Occasionally a sample may need to be referred from the Blood Transfusion Laboratory to the Irish Blood Transfusion Service (IBTS) reference laboratory for additional testing/ crossmatching. This could result in a delay in blood provision. If a sample needs to be referred to the IBTS, BT staff/ On-call staff will notify the nurse in charge of patient.

10.5 Specimen Receipt in the Blood Transfusion Laboratory

Specimens from patients for elective surgery ideally should be received before 14.00 hours on the first routine working day before surgery. If specimens are received after this deadline, grouping, screening and if necessary crossmatching may not be complete before 10.30 the following day.

10.6 Two Separate Specimen Requirement to Determine Blood Group Pre 1st Transfusion

All patients should have had two blood groups confirmed on the laboratory information system pre their 1st transfusion. This is to eliminate the risk of an ABO incompatible transfusion due to sampling error. These specimens need to be taken on two separate occasions, ideally by two different people if same is possible.

10.7 Specimen Acceptance Criteria in Blood Transfusion

1. The patient's Type & Screen specimen (7.5 mls EDTA) arrives in the Blood Transfusion Department in a sealed bag.

   Ref.: LS-GEN-0001 Specimen Collection & Handling

Ref.: LS-GEN-0002 Specimen Transportation

2. The specimen must have a ordercom barcode label attached which contains the following details:

- Patients Surname and First name
- Date of birth
- Medical Record Number (MRN)
- Date and time of specimen collection
- Gender
- Test required

If a telephone request is made in an emergency, it must be followed up with an electronic order on PERL

3. If a specimen is rejected, the relevant ward will be informed of rejection and a repeat specimen requested.
4. Unlabelled specimens or insufficient specimens will be rejected and a repeat specimen requested.
5. Grossly haemolysed or lipaemic specimens or incorrect specimen container type are not suitable for testing. Relevant wards will be notified of rejection and request repeat specimen.

10.8 Specimen Stability

Patients' specimens are refrigerated at 2-8oC after testing and may be used for further cross-matching once the request is received and the transfusion will be complete within 72 hours of the specimen being taken.

10.9 Ordering Blood Components & Products

Red cells are ordered placing an order through PERL. The number of units required, the date the blood is required for, any special requirements e.g. CMV seronegative, irradiated, and the reason for the request must be indicated in the order.

If additional crossmatching or product issue is required on the primary specimen, a request may be made initially by phone to the Blood Transfusion Laboratory stating the name of the patient, MRN and additional tests and/or product and quantity required. This request will still need to be followed up with a PERL request for blood and blood products to be issued to the patient. There is a dedicated telephone line for use by Theatre only, the number is 8399.

10.10 Collecting and Returning Blood Components & Products

Storage of issued blood components/products for collection along with the laboratory report is as follows in the Blood Transfusion Laboratory.

Component/Product	Temperature	Storage
Red Cells	4ºC	Blood Issue Fridge
Platelets	22ºC	Platelet agitator
Octaplas	4ºC	Blood Issue Fridge
Fibrinogen concentrate	4ºC	Blood Issue Fridge
Albumin	<25ºC	Blood Issue Fridge
Recombinant VIIa Novoseven	<25ºC	Blood Issue Fridge
Octaplex (PCC)	<25ºC	Blood Issue Fridge

Table 17: Storage of Blood Components Products

The requester (Doctor) of the blood components / products must bleep the porter and request the collection of blood. A blood collection slip containing the patient's details and the quantity of product required must be given to the porter. Alternatively the completed collection slip may be sent to the laboratory in the chute where the porter collects it on entering the Pathology Department.

The porter proceeds to the Blood Transfusion Laboratory, removes the blood component/product from the relevant storage area as outlined above, checking the

patient's name, MRN and date of birth on the collection slip, laboratory report and label on the issued component/product. The porter must scan the blood component/product out of the laboratory using the Blood Track system. In the event of a blood track malfunction/ break down please use LF-BT-0049 Logbook of manual tracking of blood components/products in the event of blood transfusion Blood Track System Failure.

The blood components/products are transported within the hospital in the specific blood transport bag. The blood components/products are delivered to the nurse on the ward to process.

In the event that the nurse/requester is not present to accept the blood components/products or if the porter is requested to return them to the blood transfusion fridge, the blood components/products must be returned to the Blood Transfusion Laboratory and scanned back into fridge and placed in the storage area where first acquired (see Table 17 above).

Any blood components/products which are not going to be used immediately must be returned to the Laboratory.

10.11 Emergency Group O Rh D Negative

In the event of an emergency situation, four Group O Rh D Negative un-cross-matched red cells are available for immediate use. A red cell order for the patient must be placed in PERL to ensure that the units are available in the patients TAR records. Where possible a type & screen PERL request and specimen from the patient should be sent to the laboratory **before** the blood is transfused to establish the patients' pre transfused blood group. If the patient has a historical blood group once this sample is processed and all criteria for electronic issue are met blood can be issued electronically. Where the patient has no known blood group, two separate samples are required see section 7.6.

These units should be collected by trained staff members who must scan their ID badge into Blood Track and select the 'Emergency Blood' icon on the screen. Patient details are not required in this instance when removing this blood.

Where a patient has special requirements e.g. CMV-Irradiated and /or antibodies, the responsibility to transfuse this emergency Group O Rh D Negative red cell lies with the Medical Officer in charge. All incidents where blood is issued as an emergency are audited by Haemovigilance.

10.12 Transfusion Reaction Investigation

Any unfavourable response by a patient to the transfusion of blood components/products may be described as a transfusion reaction or Serious Adverse Reaction (SAR). Not all reactions are associated with red cell destruction following in vivo formation of antigen-antibody complexes, however, transfusion reactions that are caused by such destruction are among the more serious that can occur. Transfusion reactions (SARs) may be divided into four broad categories

- Acute immunologic
- Acute nonimmunologic
- Delayed immunologic
- Delayed nonimmunologic

If a transfusion reaction is suspected, the transfusion should be stopped promptly to limit the volume of blood infused.

It is the responsibility of the Mater Private Hospital to ensure that the organisation complies with the requirement of the EU Blood Directive in identifying, investigating, managing and reporting any adverse event or reaction that has occurred with the transfusion of blood or blood products.

It is the responsibility of the medical and nursing staff:

- To educate patients with regard to the possible reactions associated with the transfusion of blood or blood products.
- To correctly identify, fully investigate and manage any reaction, adverse event or near miss.

- To report all transfusion reactions and adverse events, near misses and non-compliances to the Haemovigilance Officer, hospital blood transfusion laboratory (as appropriate) and also the hospital quality team by completing the hospital PERL QRM Incident report.

In cases where there is suspected transfusion reaction, a full investigation as to the cause must be undertaken.

- The transfusion should be stopped immediately, keeping the blood pack and its contents, together with blood administration set for examination by the staff of the blood transfusion department.

The following should be sent to the Blood Transfusion Laboratory as part of the investigation of the suspected reaction:

- A post transfusion Type and Screen specimen
- The implicated blood components/products
- The giving sets used
- Specimens for an FBC, coagulation, Urea & Electrolytes LDH & liver profile, blood cultures and the first voided urine specimen.
- All required tests should be completed at the time of reaction and sent to the laboratory accompanied by the Transfusion Reaction Form (MPH-HAE-095). Complete DOC REC in TAR.
- Alert Haemovigilance Staff or in their absence the staff of the blood transfusion laboratory, and follow policy NUR-HAE-013 " Policy on the management and reporting of reactions, adverse events, near misses and non-compliances associated with the transfusion of blood and blood products". Haemovigilance will follow up and discuss all adverse events, reactions, near misses and non-compliances with the Haematologist at the monthly Haemovigilance/Quality meeting or the Blood Transfusion Committee meeting. Each event will reported on, have relevant corrective and preventative actions carried out and each event closed out.

Ref.: NUR-HAE-013 Policy on the management of reactions, adverse events, near misses and non compliances associated with the transfusion of blood and blood products.

The IBTS is immediately contacted and the Rapid Alert Notification System is implemented where the following reactions are suspected:

- Bacterial contamination of blood components/ products transfused
- Transfusion related acute lung injury
- Post transfusion viral infection
- Other post transfusion infections e.g. malaria

10.13 Haemovigilance Service

A Haemovigilance service is available in the hospital. All Haemovigilance policies and procedures are available on the hospital MPH intranet under the heading "Documentation", then "Haemovigilance". Further information can be obtained by paging the Haemovigilance Nurse at 8311 or by contacting the hospital blood transfusion laboratory at 8131.

10.13.1 Written Consent for Transfusion

Except in emergencies the patient must be prepared for the transfusion by explaining the reason for transfusion. Discussion must include the benefits, risks and alternatives to transfusion as appropriate and allow for any questions/ concerns the patient may have. Ensure the patient has read and understands the hospital patient information leaflet on Blood Transfusion.

10.13.1.1 Consent at Time of Admission

The admitting or PAC nurse must give all surgical patients (who require a type & screen), oncology and haematology patients a patient information leaflet on blood transfusion. Staff will give all medical patients at departmental level.

10.13.1.2 Consent for Surgical Patients

Written informed consent must be obtained as part of the patients surgical consent process. In PERL this consent is obtained by medical staff on their IPads which uploads into the patients charts. This surgical consent covers the patients consent for blood transfusion if a transfusion is required as part of their treatment.

This consent for blood transfusion is also valid in the post operative ward setting for 90 days from date of signing consent.

10.13.1.3 Consent for Elective Transfusions

Written informed consent for medical/elective transfusion is obtained from the patient on each current admission. This is on Consent Form for Blood and Blood Product Transfusion in PERL. This consent is obtained by medical staff on their IPads which uploads into the patients charts.

EHR to include:

- Patients name, DOB, MRN
- Patient signature, date and time
- Doctors signature, MCRN number and date and time
- Reason for transfusion

Written consent is ticked in Verify in TAR

Ref.: NUR-HAE-001 Policy on the Use of Blood and Blood Products & Blood transfusion patient information leaflet MPH 2154

11. MICROBIOLOGY

11.1 General Information

The extension for Microbiology is 8133.

The extension for Molecular Microbiology is 8118 (office) /1898 (Laboratory).

To request a microbiology consult please contact the laboratory with the patients details, preferably before 12.00. The details will be passed on to the consultant. Consults can also be made directly via PERL.

Results will generally be available from 11am. Please refrain from calling the laboratory before this time.

The cut off time for culture set up is 16:00 Monday-Friday and 12:30 on Saturday. Samples received after this time may be delayed by 24 hours in reporting.

11.2 Requesting Microbiological Investigations

1. Please request Microbiology test via PERL and label the appropriate sample
2. Urgent request must be accompanied by a verbal request and handed to a medical scientist.
3. Site and specimen type are required; failure to provide may result in rejection of sample.
4. All additional tests must be requested by phone and an order com sticker sent.
5. Requests for additional culture of fastidious organisms, (e.g. *Neisseria* species) must be requested the day the specimen is taken.
6. Requests for additional tests on all other specimens must be received within 24 hours.
7. Requests for additional tests that are not routinely carried out in the laboratory should be discussed with the consultant microbiologist.
8. Requests for SARS-CoV2/FLU/RSV testing are only available on symptomatic patients or if pre-approved by the Consultant Microbiologist, Infection control nurse or house sister out of hours

9. All urgent SARS-CoV2/FLU/RSV samples must be hand delivered to a medical scientist
10. The hospital chute system must NOT be used for the transport of SARS-CoV2/FLU/RSV specimen to the laboratory.

11.3 On-Call Service Repertoire in Microbiology

- Outside normal working hours the emergency service is covered by the Medical Laboratory Scientist on call, who is contactable by mobile phone through reception or security. All tests authorised are available on-line.
- Positive blood cultures are processed on call by medical scientists.
- SARS-CoV2/FLU/RSV Testing is performed on clinically suspicious urgent cases, non-urgent will be refrigerated and testing carried out the following working day.
- Specimens of CSF received out of normal working hours will be referred to MMUH up until 8PM Monday to Friday. **The consultant Microbiologist on-call should be consulted prior to taking any CSF out of hours.**
- Pregnancy testing may also be carried out on-call.

11.4 Reports

1. A member of the technical staff will telephone urgent results to the requesting clinician or ward (if verbally requested), or to the microbiology consultant.
2. Important results such as positive blood cultures, salmonella isolates, etc. will be telephoned to the relevant consultant and/or infection control on the day of isolation as preliminary results.
3. Final reports will be issued on the day of completion via EMR
4. Where possible, please do not telephone for results before 11.00am to allow for cultures to be read.
5. Authorised results are available on-line to the wards.

11.5 Specimen Collection

All containers/swabs including red top liquid swabs for SARS-CoV2/FLU/RSV testing may be obtained from the Stores Department. Blood cultures, Viral swabs, Chlamydia swabs and Transwabs may be obtained from the Microbiology Department between 09:00 and 17:00.

11.6 Referral Antibiotics

TEST	ABBREV	SPECIMEN VOLUME	SPECIAL PRECAUTIONS	TURN AROUND TIME	REFERENCE RANGES
Teicoplanin	Teic	7.5ml clotted	**Trough levels to be taken only,** These are taken immediately before the dose	These are referred to the microbiology department, MMUH.[1]	The therapeutic dose is 20-30mg/l, for MRSA infective, infecting endocarditis and osteomyelitis treatment

[1]These are referred to the microbiology department, MMUH. Specimens must arrive to the microbiology department MMUH by 3.30pm for analysis (routine working hours). There is no on-call service available for analysis. Special arrangements for Saturdays, Sundays and Bank Holidays are in place; specimens must arrive to the microbiology department MMUH by 9:30 am on these days. Results are phoned to the requesting ward.
Other antibiotic assays NOT performed in house please discuss with department prior to sending.

11.7 Specimen Collection

11.7.1 SARS-COVID-19/Influenza/ RSV Testing

All testing for SARS-CoV2/FLU/RSV should be conducted in consultation with a healthcare provider. The tests for these four respiratory viruses SARS-CoV2, Influenza A, Influenza B and RSV are all conducted on the same multiplexed platform and are reported in tandem.

Collect specimen as soon as possible once a decision has been made to pursue testing, regardless of the time of symptom onset.

For initial diagnostic testing for SARS-CoV2/FLU/RSV, collecting and testing an upper respiratory specimen is recommended. The following are acceptable specimens: nasopharyngeal (NPS) and/or Oropharyngeal (OPS)(NPO) Swab specimen collected by a healthcare provider.

Swabs should be placed immediately into a sterile transport tube containing 3mL of either universal transport medium (UTM), Red Top). The sample type should be input via PERL upon ordering. Regardless of the virus required for testing (SARS-CoV2, Influenza A, Influenza B or RSV) all four viruses will be tested and reported simultaneously.

Other sample types need to be discussed with the laboratory contact 8133.

11.7.2 Blood Cultures

1. Obtain 2 blood culture bottles and 1 blood culture pack from the Specimen Reception area of the Pathology Laboratory.

- *Note:* The BacT/Alert 3D blood culture system is used in the Mater Private Hospital. Two bottles are used; FA for aerobic and facultative anaerobic microorganisms and FN for anaerobic microorganisms. FN contains contain 32ml of complex media and 8ml of a charcoal suspension. Bottles contain an atmosphere of nitrogen under vacuum. FA contains 22ml of complex media and 8ml of a charcoal suspension, Bottles contain an atmosphere of CO2 in oxygen. It is suitable for the isolation of aerobic, anaerobic organisms and fungi.

2. Prior to use, the BacT/ALERT FN/ FN Culture Bottles should be examined for evidence of damage or deterioration (discoloration). Bottles exhibiting evidence of damage, leakage, or deterioration should be discarded. The media in undisturbed bottles

should be clear, but there may be a slight opalescence or a trace of precipitate due to the anticoagulant SPS.

3. Prior to touching a patient, hand hygiene must be completed by the phlebotomist, by washing hands or using alcohol hand rub (moment 1 - before patient contact). Identify a suitable vein (usually on the arm) from which to draw blood from the patient. Clean hands.
4. Open sterile pack and set up sterile field, attaching the devices needed together in preparation for the procedure
5. Apply the single use Tourniquet above the blood-sampling site and swab the skin over the vein vigorously for 1 minute with a 2% chlorhexidine in 70% alcohol single use sponge/swab (chloraprep). Allow to dry for 30 seconds.
6. Remove the flip-lid seal from the blood culture bottles and swab the rubber stopper thoroughly with sanicloth CHG 2% swab. Clean hands using alcohol hand gel or by washing them and Apply - sterile gloves. Then using aseptic non-touch technique, take a sterile butterfly safety device, Insert the butterfly into the vein of the patient, taking care not to contaminate, repalpate or touch the needle insertion site and obtain up to a 10ml blood specimen (4ml for a paediatric bottle). If you need to palpate the vein again it's important to remove gloves, reclean hands and apply a new set of sterile gloves.
7. Place the collection cap over the blood culture bottle and fill to the required level. Then repeat for bottle two. Always collect aerobic (green) before anerobic (orange). (If you need to collect the blood via a syringe and not from the closed circuit you should enter the blood into the anerobic bottle first and then the aerobic bottle).
8. Once the blood is collected, disconnect blood culture section and proceed to take any blood samples needed
9. Remove the tourniquet first, Then carefully remove the butterfly, ensuring the safety cover is applied as you remove it
10. Place a plaster or dressing over the blood-sampling site.

11. Place used needles and sharps into the CinBin provided. Any other clinical waste must be disposed of directly into yellow risk waste bin.
12. Remove gloves, clean hands.
13. Label the bottles with their corresponding com labels. Scan the bottle barcodes into the phlebotomy order on PERL.
14. Transfer the samples directly to the Microbiology discipline of the Pathology Laboratory. **Never send Blood culture bottles in the Chute system.**
15. Outside of routine working hours: Please bleep a porter as soon as possible after collecting the specimen. The porter will transport the blood culture bottles to the laboratory and load the bottles on to the Bac-T alert system.

11.7.3 Urine

Please send an MSU (midstream specimen of urine), in order to avoid contamination of the specimen. Please send all such specimens in a CE marked (Aseptically/ clean room manufactured) container (yellow capped) container.

1. Clean the area around the penis or vagina with a tissue.
2. Begin urinating into the toilet bowl.
3. Stop and urinate into the sterile container until it is half full.
4. Finish urinating into the toilet.
5. Close the bottle tightly, label bottle clearly with your name and date.
6. Wash hands.
7. Place in biohazard bag and seal.
8. Transport to the Laboratory as soon as possible after collection.
9. Place in the designated refrigerator after routine working hours.

For pregnancy test and investigations for AFB in urine, please send early morning specimens of urine.

NOTE: *For AFB investigation of urine, send the full early morning collection.*

11.7.4 Viral Testing

Swabs: Send in universal transport medium (UTM).

SARS-Covid-19/Influenza/RSV testing send a Naso/Oro-pharyngeal sample in a Liquid Universal Transport Medium (red top)

*Full Repertory Screen Send a Naso/Oro-pharyngeal sample in a Liquid Univeral Transport Medium (red top)

*CSF: Send in sterile universal container

*Faeces: Send in sterile capped universal container

Testing kits for saliva testing for Measles IgM are available on request, please allow plenty of time for the laboratory to acquire kit. Blister Fluid: Spread directly on a slide, if EM is requested.

Refer to section 8.9 below

If in doubt about any specimen collection, ring the Laboratory for advice.

*NB: Transport medium is not added, some viruses may be thermoliable please send to laboratory ASAP| for storage at 2-8°C or store at 2-8°C if delay in transport, CMV urine request may require storage at -20°C.

11.7.5 Chlamydia Isolation

If you wish to request Chlamydia investigations please obtain the special Chlamydia swab / urine collection kit from laboratory.

11.7.6 CSF

Please send specimens of CSF, for the investigation of suspected meningitis. Send specimens in sterile, universal containers. ***Please note all CSF samples should be hand delivered to the laboratory and handed to a medical scientist. Do not use pneumatic chute system.***

- Collect 3 samples, label bottle 1 (first drops), 2 and 3 (last drops), of approx. 1mL of CSF
- Samples 1 & 3 will be used for cell count.

- Sample 2 Biochemical determination (Protein and Glucose), samples with high cell counts may not be suitable for protein testing, glucose cannot be tested >1hour.
- Sample 3 for culture and Gram stain (if required)

A 4th sample may be sent if further testing is required i.e. viral studies

NOTE: Always notify the Microbiology Department when you have taken a CSF. The specimen should not be refrigerated. **The consultant Microbiologist on-call should be consulted prior to taking a CSF sample out of routine hours.**

11.7.7 Pus

Send Pus in a sterile universal container wherever possible. Send pus swabs only if pus is difficult to collect.

11.7.8 Fluids e.g. Pleural, Joints

Place aliquot into a sterile container.

Fluids for cell counts only accepted if in EDTA container, this will prevent clot formation.

11.7.9 Sputum

Please send a purulent / mucopurulent specimen. Do not send saliva for culture unless from ITU and no other specimen can be obtained. Special wide mouth sputum containers are available.

11.7.10 Swabs

Transwabs can be obtained from the microbiology department.

- Pressure sores

These should be swabbed if there is evidence of infection e.g. cellulitis, pus, inflammation. Do not swab as a routine.

- Swabs (drain)

These should be taken only if there is evidence of infection, e.g. cellulitis, discharge of pus.

- Ulcer swabs

Ulcers should only be swabbed if there is evidence of infection e.g. if there is cellulitis or pus formation.

Do not swab as a routine.

- Investigation of Whooping Cough

Please send Per-nasal swabs, ordinary throat or nose swabs are unsuitable.

Special 'fine' swabs are available from microbiology and you should contact the department prior to taking the specimen. Samples will be referred for PCR testing.

11.7.11 Stool Specimens

Please send stool specimens for culture/parasitology/virology in separate universal containers when possible.

Formed stool samples will not be tested for *C. difficle* or Norovirus unless specifically requested by consultant microbiologist

In-patient testing for routine C&S will not be carried out on patients with a hospital stay >3 days unless requested by consultant microbiologist.

Please supply travel information and any supporting clinical information for parasitology requests (routinely Giardia and Cryptosporida only tested unless further information supplied).

11.7.12 Faecal Immunochemical Test (FIT)

Home patient testing should be conducted using the Hemosure home collection kit and sent to the laboratory as per kit instructions in the Accu-Reader collection tubes.

In house testing of patients can be performed using these kits (available via stores) or sent in universal container for sampling in the laboratory.

11.8 Specimen Stability and Storage

SPECIMEN	STORAGE AND SPECIMEN LIFE
Blood Cultures	These should arrive in the laboratory within 4 hours of collecting. Out of routine hours bleep a porter as soon as possible after specimen collection.
SARS CoV-2 / Influenza/RSV	Samples may remain at room temperature up to 8 hours, then stored 2-8°c for up to 72 hours.
CSF	Immediate processing of CSF specimens is always indicated. Please advise the laboratory or the on-call staff when you have taken a specimen. If the specimen is more than 2 hours old on receipt the cell count may not be accurate due to cell disintegration. Glucose analysis must be done as soon as possible; it cannot be performed on specimens more than 1 hour old.
FIT Collection Tubes	Once the collection tubes are inoculated with patient stool the sample is stable for 30 days at room temperature prior to testing.
All other Specimens	Urine, swabs, fluids, stool, tissue sputum etc. may all be stored overnight if refrigerated. Please leave all such specimens in the specimen fridge. **Microbiology specimens should not be put in the freezer.** They will be collected and processed by laboratory staff each morning.

Table 18: Specimen Stability & Storage

11.9 Notes on the Collection of Specimens for Virus Investigation

1. All test requests are ordered on PERL and each sample is labelled with a barcode ordercom label with all patient demographic information and the test requested.
2. The table that follows is designed to help in collection of correct specimens for virus investigation

Disease	Specimen	Test for Causative Virus or other agent
Aseptic meningitis encephalitis	C.S.F. at 4°C, Faeces at 4°C Throat swab in transport medium at 4°C *Serum: Acute/convalescent*	Culture for E.C.H.O., Coxsackie, herpes, mumps, polio virus. Antibodies to virus isolated from other specimens.
Lower Respiratory Tract Infection	Throat swab in transport medium at 4°C. Laryngeal swab in transport medium at 4°C. Sputum at 4°C.	Immunofluorescence for sputum, BAL, R.S.V., influenza, para-influenza, adenovirus, some enteroviruses, cytomegalovirus.
	Throat washing taken at bedside with 50% glycerol.	Culture for R.S.V.
	Serum: Acute/convalescent	Antibodies to isolated virus from above specimens and mycoplasma, Q.fever, psittacosis, influenza, para-infueneza, R.S.V. Chlamydia pneumonia.
Myocarditis Pericarditis	Faeces Pericardial effusion at 4°C *Serum: Acute/convalescent*	Culture for Coxsackie B antibodies to psittacosis, coxiella burnetti, (Q.fever), Coxsackie if isolated from specimens.
Rubella / VZV / Parvovirus / Measles / Mumps (1) Normal adult (2) Pregnancy	Serum. Consult Microbiologist regarding further investigations.	Rubella / VZV / Parvovirus / Measles / Mumps IgG / IgM antibodies.

Disease	Specimen	Test for Causative Virus or other agent
Measles IgM	*Saliva*	Measles IgM testing
VZV	*Vesicle fluid*	VZV PCR
Jaundice (unexplained)	*Serum: Acute convalescent*	Antibodies to toxoplasma, cytomegalovirus, herpes, adenovirus, leptospirosis.
Gastroenteritis	Loose/Liquid stool	Norovirus, Rotavirus
Upper Respiratory Tract Infection	Nasopharyngeal/Oropharyngeal Swab In universal transport medium (red top)	SARS CoV-2/Influenza A/Influenza B/ RSV, Full respiratory panel also available upon request with Consultant Microbiologist
Conjunctivitis	Conjunctival swab in transport medium at 4°C Conjunctival scraping in transport medium at 4°C	Culture for herpes, adenovirus

Table 19: Samples for Virus Investigation

NB: *Specimens for virus culture should reach the laboratory within one to two hours of collection and should be stored in the fridge before transportation*

11.9.1 Nasopharyngeal/Oropharyngeal swab

A swab should be taken of Oropharyngeal area then of the nasopharyngeal area and place in universal transport media (red top swab)

11.9.2 Throat Swabs

Well moistened swabs should be taken and broken into virus transport medium. This is available in the laboratory.

11.9.3 Throat Washings

Obtained by asking the patient to gargle 1 - 15 ml sterile saline. This is then collected in a sterile screw-capped container.

11.9.4 Faeces

Specimens should be collected in a sterile screw-capped container.

11.9.5 Sputum

Specimens should be collected in a sterile screw-capped container.

11.10 Notes on Specimens for Bacterial Culture

SPECIMEN	STORAGE TIME AND TEMPERATURE
Urine	Overnight – may be left at 4º.
Swabs	Overnight – may be left at 4º.
Sputum	Overnight – may be left at 4º.
Stool	Overnight – may be left at 4º.
Fluids	Overnight – may be left at 4º.

Table 20: Specimen Storage

1. Specimens should reach the laboratory by 4.00 pm on weekdays and 11.30 am on Saturdays.
2. Please contact the laboratory regarding urgent specimens after this time.
   NB: *Only urgent specimens are processed on Saturday mornings.*
3. Specimens which cannot be processed after collection should be kept in the refrigerator, except:
   - Specimens of cerebro spinal fluid - keep at room temperature until bacteriological culture and microscopy complete.
   - Swabs for G.C. - should be cultured immediately,
     PCR testing using a suitable collection kit (urine / swab) is a preferred method for initial screening as it is sensitive and stable prior to testing.
4. Please contact the Consultant Clinical Microbiologist when unusual or opportunistic infection is suspected, especially in patient with Acquired Immuno Deficiency

Syndrome, post transplant, on chemotherapy, or otherwise immuno-suppressed, for advice on specimen collection.

11.11 Septicaemia and Endocarditis

The isolation of the organism is essential to the correct management of these patients and every effort should be made to withhold antibiotics until blood cultures have been taken. Suspected cases of endocarditis should be noted in the specimen comment at ordering to ensure appropriate incubation times are applied. Septicaemia may follow procedures such as genito-urinary manipulation, sigmoidoscopy, bronchoscopy or may occur in other pathological conditions. At least two blood cultures should be taken, to reduce the risk of contamination. Blood cultures are also indicated in the following conditions:

- Acute purulent meningitis
- Acute osteomyelitis
- Pneumococcal pneumonia.

11.11.1 Timing and Numbers of Cultures

Cultures must be taken before antibiotic therapy commences. When treatment is urgent, two separate cultures may be taken within the hour. Where treatment can be delayed, three cultures should be taken over a 24-hour period, and if these are negative, a further three cultures taken. When a patient suffers from occasional rigors and is afebrile in the intervening period positive cultures are most likely when taken at the time the patient feels the rigor coming on.

11.11.2 Method

The BacT/Alertblood culture system is in use.

See section 8.7.1 for blood culture collection.

11.11.3 Common Infecting Organisms

- *Streptococcus viridans*
- *Enterococcus faecalis*

- *Staphylococcus aureus*

11.11.4 Less Common Infecting Organisms

- Gram negative enteric organisms
- Q. Fever (C. Burnetti) Serological diagnosis, demonstration
- Psittacosis of rising titre
- Brucellosis
- Bartonella
- Chlamydia Pneumoniae
- Toxoplasmosis

11.11.5 Post-Operative Cardiac Surgery

- Coagulase negative staphylococci, fungi.

11.11.6 Immuno compromised patient

- Gram negative enteric micro-organisms
- Coagulase negative staphylococci
- Fungi

11.12 Respiratory Infections

11.12.1 Upper Respiratory Tract

Specimens - throat swab, laryngeal swab. The majority of these infections are caused by viruses.

- ***Common Infecting Organisms***
  - *Streptococcus pyogenes*
  - *Vincents Organisms*
  - *Candida albicans*

NB: Culture for *C.diptheriae* is not done routinely. Please notify the Laboratory .

11.12.2 Lower Respiratory Tract

Specimen: Sputum (in screw-capped container only).

- Bronchial Washings/brushings (in screw-capped container only).
- Urine for *Legionella / Str. pneumoniae* antigen testing

- ***Chronic Bronchitis***

Three specimens of sputum should be examined as this increases the isolation rate of *H.Influenzae* significantly. Exacerbations are caused by *H.influenzae*, *Strep.pneumoniae*, *Moraxella catarrhalis*

NB: Where the patient has difficulty in producing a specimen of sputum postural drainage and physiotherapy may be required to obtain a suitable specimen. Salivary specimens are unsuitable for culture and will be discarded, unless from ITU.

- ***Pneumonia***

A gram stained film of sputum may be helpful in making the diagnosis and choosing a suitable antibiotic prior to results of cultures. The infecting organism may be isolated from blood culture in a third of cases.

- ***Infecting Organisms***

Gram stains are available upon request.

Strep.pneumoniae	Urine for Str pneumo antigen
Staphylococcus aureus	
Klebsiella pneumoniae	
Pseudomonas aeruginosa	
Mycoplasma pneumoniae	Serological diagnosis
C.burnetii (Q Fever	Serological diagnosis made on rising titre
Psittacosis	
Pneumocystis carninii	Indirect fluorescent test available
Cytomegalovirus	Please consult Microbiologist

Legionella culture *Legionella serology*	If legionnaire's disease is suspected please notify the laboratory as soon as possible. Special culture medium is required for isolation from sputum or bronchial lavage. Specimens for culture are referred. Urine for legionella antigen
Bronchiectasis	
Staphylococcus aureus	
Bacteroides species	
Cystic Fibrosis	
Pseudomonas aeruginosa, Burkholderia cepacia	
Other gram negative enteric organisms	
Staphylococcus aureus	

Table 21: Gram Stains

11.13 Meningitis

Collect 1 ml of CS.F. into each of three sterile containers. Label and return to laboratory for immediate examination. Blood cultures should also be taken.

Findings

TEST	NORMAL	ACUTE BACTERIAL MENINGITIS	TUBERCULOUS MENINGITIS	ASEPTIC MENINGITIS
Appearance	Clear/Colourless	Turbid	Clear/Opalescent	Usually Clear
Protein	15-45 mg/dl	Greatly increased	Moderately increased	Slightly increased
Glucose	2.6 – 4.3 mmol/l	Greatly reduced	Reduced	Normal
White cell	0-3 per µl	Greatly increased	Increased mainly	Increased lymphs

TEST	NORMAL	ACUTE BACTERIAL MENINGITIS	TUBERCULOUS MENINGITIS	ASEPTIC MENINGITIS
count		90% polymorphs	lymphs	
Culture	Sterile	Casual bacterium isolated	*M. tuberculosis* isolated	Negative

Table 22: Blood Culture Findings

NB: Specimen for Virus isolation should be kept at 4°C to await transport to the virus reference laboratory.

- **Common Infecting Organisms:**
  - *N.meningitidis*
  - *H.influenzae*
  - *Strep.pneumonia*
  - *Listeria monocytogenes*

Test	Specimen Required	Comments
Blood for PCR	EDTA specimen. Older children and Adults 2.5-5.0 ml.	This specimen must be collected on admission as antibiotic treatment rapidly causes this specimen to revert to negative.
CSF for PCR	A small aliquot of the neat CSF specimen: a minimum 100µl (8-10 drops).	Store and transport in a small well-sealed container, e.g. an eppendorf tube.
Paired Specimens for serology	Clotted blood Specimens	*Acute Phase:* Collect within 48 hours of admission. *Convalescent Phase:* Ideally collect on day 14-21.

Table 23: Specimens for Non-Culture Diagnosis of Invasive Meningococcal Disease

11.14 Wound Sepsis

A wide variety of organisms may cause would infection.

Anaerobic organisms are especially likely to infect wounds after abdominal and gynaecological surgery. Commonest organisms found are:

- *Staphylococcus aureus.*
- *E.coli.*
- *Klebsiella species.*
- *Bacteroides species.*

- *Specimen*

1. Pus.
2. Moist swab.

NB: For isolation of anaerobic organisms, swabs or specimen of pus should be freshly taken and sent to the laboratory for immediate processing.

11.15 Urinary Tract Infection

Many different organisms cause urinary tract infection. Their sensitivity pattern may be unpredictable and treatment should be guided by results of antibiotic sensitivity testing.

- *Specimens*

Male: Clean midstream specimen.

Female: 1. Swab the vulva with sterile water or saline.
2. Take clean catch midstream specimen.

NB: Specimens should be examined without delay. If delay is unavoidable they should be placed in the refrigerator in the laboratory.
Diagnosis and appropriate treatment is critically dependent on getting correctly taken specimens.

Interpretation of Results When Patient is Not on Antibiotics.

	Normal	**Contaminated**	**Infected**
Bacterial Count/ml	Sterile	10,000	100,000 Counts between 10,000 - 100,000 may be associated with symptomatic infection.

White Cell Count	10/µl	--	No count is diagnostic. Acute infection usually raised. Chronic infection usually low.

Table 24: Symptomatic Patients

NB: Diagnostic criteria of asymptomatic bacteriuria:

- two consecutive clean voided specimens
- revealing 100,000 org/ml
- with the same organisms in both specimens.

11.16 Venereal Disease

NB: All cases should be referred to the STD clinic MMUH or the Infectious Diseases Physician

- **Gonorrhoea**

Please contact the laboratory.

	Specimen	Sample Requirements
Screening	Urine / Urethral / Rectal / Cervical / Eye swabs	Swab or decant Urine into chlamydia / gonorrhoea transport media for PCR
Male	Urethral swab Rectal swab	Transport swab to the laboratory immediately. Make films separately.
Female	Take cervical, urethral and rectal swabs.	Swab into chlamydia / gonorrhoea transport media for PCR

Table 25: Gonorrhoea Specimens

- **Trichomoniasis**

Female: Swab of vaginal fluid from posterior fornix.

Male: Urethral secretion. First early morning urine specimen. (NB: Not M.S.U.)

- **Candidiasis**

Vaginal Swab

Candida albicans may present as a saprophyte in the normal female genital tract. In pregnancy, oral contraception, tetracyclines or immuno-suppressive therapy, they may be of pathogenic significance.

- **Bacterial vaginitis / Gardnerella vaginalis**

High Vaginal swab.

11.17 Fungal Infections

- **Fungal Infections of the Lung**

Pathogens *Candida albicans*

Aspergillus fumigatus and other related species.

Specimens

1. Sputum
2. Serum for precipitins to *Aspergillus fumigatus* and Farmers Lung antigens.
3. Skin tests.

Groups	Skin Test Reaction		Eosinophilia	Precipitation
	Immediate	Late		
Asthma	+	-	+	-
Allergic Bronchopulmonary Aspergillosis	+	+	+	+ (1-3 arcs)
Mycetoma	±	±	-	++ (3-8 arcs)
Mycetoma + Allergic Bronchopulomary Aspergillosis	+	+	+	++ (3-8 arcs)
Invasive Aspergillosis	-	-	-	±
Intrinsic Alveolitis	-	-	-	-

Table 26: Diagnostic Tests for the Major Groups of Pulmonary Aspergillus's

Dermatophytes:	*Trichophyton* species *Epidermophyton* species *Microsporum* species
Specimens:	Skin Hair Nails

Table 27: Fungal Infections of the Skin, Hair and Nails will be sent for referral testing.

- *Skin Scrapings*

Clean area with 70% isopropyl alcohol allow to dry. Take scrapings from active periphery of lesion into a clean piece of paper, fold, laboratory el and send to laboratory or take scrapings onto a glass slide. Cover with second glass slide. Tape, label and send to laboratory.

- *Hair*

Take hair stumps, broken hairs, lusterless hairs; extract with forceps and extract any intrafollicular fragments with a Hagdorn needle. Skin scrapings should also be taken. Place in clean screw capped container. Label and send to laboratory.

- *Nails*

Clip off whole thickness of affected nail. Remove debris beneath infected nail. Place in a clean screw capped container. Label and send to laboratory.

***NB*:** Please contact consultant Microbiologist where tropical infection is suspected or when unusual or rare pathogens are requested to be sought. Identification and sensitivity testing on positive fungal growth will be sent for referral testing which may add up to 4 weeks to the TAT.

11.18Gastroenteritis

Specimen: Collect faeces in a screw-capped container. Well stained rectal swabs are acceptable if no faeces is available. This should be followed by a faecal specimen.

Specimens from inpatients admitted to hospital >3days before date of specimen, are only processed for Norovirus or C.difficile Toxin A+B unless otherwise requested.

Salmonella:	(a) Enteric group:	*S.typhi, S. paratyphi* A.B.C.
	(b) Food poisoning:	*S.typhimurium*, etc.
Shigella species		
Campylobacter		
Enteropathic E.coli		
Entamoeba histolytica (on request)		
V.cholera (not sought routinely, please contact Laboratory).		
E. coli 0157		

Table 28: Common Pathogens

Food Poisoning

Specimen: Faeces in screw-capped container.

Food Specimens.

Common Pathogens
Staphylococcus aureus
Clostridium perfringens
Campylobacter
E. coli 0157

NB: Please record the association with an outbreak of food poisoning when ordering in the clinical details field called "reason for exam". State age of patient and also state if patient is post-operative and on antibiotics. Please state if patient is Immune suppressed.

- **Antibiotic Associated Diarrhoea**

Expected Pathogen	Clostridioides *difficile.*

Please give details of antibiotic therapy.

All diarrhoeal specimens from in-patients should have *C. difficile* Toxin A & B analysis.

Diarrhoeal specimens are defined as those that take up the shape of their container.

Formed stools should not be processed for *C. difficile* Toxin A & B unless specifically requested by the consultant or infection control nurse.

- **Helminths and Protazoa**

Specimens: Faeces (warm for *E.histolytica*).

Tests for parasitology are referred to Medlaboratory Pathology

11.19 Eye Specimens for the Pathology Laboratory

- **Conjunctiva and lids – cultures**

No topical anaesthetic. Avert lower lid and wipe sterile, moistened swab along entire lower fornix. Moisten swab with sterile saline. Use Transwab (transport medium containing charcoal to preserve delicate organisms prior to culture). Wipe lid margins with another moistened swab if lid culture is required.

In special cases swab may be placed directly onto a blood or chocolate agar plate (by arrangement with the laboratory). A different swab must be used for each eye and each site.

- **Conjunctiva and Lids – Cytology**

Instil a topical anaesthetic. A platinum spatula is flamed and allowed to cool to room temperature. The lid is averted (upper or lower) and the epithelial surface is gently scraped. Avoid any bleeding. Where there is local disease, take swab from site of maximum involvement. Spread material in a thin layer on a pre-cleaned glass slide. Fix and allow to dry for five minutes. Send all specimens to laboratory as soon as possible.

- **General ulcer (Non-viral ulcer)**

Instil topical anaesthetic. Touch dry swab to central area of ulcer. Avoid contact with conjunctiva or lid margins.

- **Cytology**

Under the slit lamp, take scrapings of the advancing edge and deeper central area of the ulcer. Spread on pre-cleaned glass slides.

- **Viral ulcer**

Scrapings are taken, as described above, from the ulcer and placed in virus transport medium, which is available in the microbiology laboratory. The barcode labelled specimen should be kept refrigerated until sent to the laboratory.

- **Endophthalmitis**

Aqueous tap 0.2ml of aqueous humor taken with 25 gauge, 5/8 inch needle on a tuberculin syringe.

Place in sterile container and send immediately to Laboratory

Vitreous tap 0.2ml of vitreous humor taken with 22 gauge needle from the site of maximum involvement.

- **Acanthamoebae**

Please contact laboratory for special culture medium.

11.20 Pregnancy Test

A urine specimen collected any time of day is suitable, but a first morning urine specimen which should contain the highest concentration of HCG is recommended especially when testing around the beginning of the first missed menses. Urine specimens may be collected in clean dry plastic or glass containers.

Urgent: - 30 mins

Routine: -1 Day

11.21 Availability of Microbiology Results

Microbiology Turnaround Times (TAT)

Test	TAT for Negative	TAT for a Positive[1]	Urgent Request[2]	On-Call[2]
Blood Culture	Initial report at 2d, Further report @ 5d	7 days	N/A	Not Available
CRE Screen	2 days	4 days	N/A	Not Available
CSF M, C&S	3 days[3]	4 days[3]	Microscopy / Gram available within 2h[3]	Within 4h[3]
Deep Wound / Tissue	Initial 3 days further report @ 10 days	14 days	Microscopy / Gram available	Not Available

Test	TAT for Negative	TAT for a Positive[1]	Urgent Request[2]	On-Call[2]
			within 2h	
Eye / Ear / Nose / Throat	2 days	4 days	N/A	Not Available
Faecal C. difficile	1 days	1 days	Within 4h	Not Available
Faecal M,C&S	4 days	5 days	N/A	Not Available
Faecal Immunochemical Test (FIT)	2 days	2 days	N/A	Not Available
Fungal Culture	10 days	1-8 wks	N/A	Not Available
Genital Swab	2 days	4 days	N/A	Not Available
HVS – High Vaginal Swab	2 days	4 days	N/A	Not Available
Joint Fluid	Initial 3 days further report @ 10 days	14 days	Microscopy / Gram available within 2h	Not Available
MRSA	2 days	4 days	N/A	Not Available
Norovirus	3h	3 h	N/A	Not Available
Peri-Cardial Fluid	3 days	7 days	Microscopy / Gram available within 2h	Not Available
Pregnancy Test	30 Mins	30 Mins	N/A	30 Mins[2]
Sputum / BAL / Other Resp samples	2 days	5 days	N/A	Not Available
Superficial wound / Pus	Initial 3 days further report @ 10 days	14 days	N/A	Not Available

Test	TAT for Negative	TAT for a Positive[1]	Urgent Request[2]	On-Call[2]
Tip Culture	3 days	3 days	N/A	Not Available
Urine M,C&S	1 day	3 days	Microscopy available in 2h	Not Available
VRE Screen	2 days	4 days	N/A	Not Available
SARS-COV2/ FLU /RSV Rapid	4h[2]	4h[2]	4h[2]	4h[2]
Turnaround times are stated for all investigations and may vary from less than two hours to several weeks, depending on the nature of the investigation. Turnaround times stated in days refer to working days, and exclude week-ends and public holidays and are from the receipt of sample in the laboratory.				
[1] May be extended depending on Clinical details / Organism isolated				
[2] Urgent/On call must be verbally requested with medical scientist				
[3] CSF specimen taken outside of routine hours **MUST** be discussed with the consultant microbiologist, MMUH cover for CSF analysis will be provided between 5pm-8pm Mon to Friday.				
[4]Batch Testing is only available during outbreaks or high demand, routine testing hours will be organised via the GCD committee and is not readily available				

Table 29: Microbiology Turnaround Times

11.22 Microbiology Critical Values

For the most up to date Critical Alert Values, please see the home page of the Hospital Intranet / Laboratory Handbook & Critical Alert Values. If you are unable to access the intranet, please contact the relevant department"

Ref.: WI-MICRO-0005 Microbiology Critical Values

11.23 Staff Self Testing

Please contact occupational health for all results of staff self-testing. These results will be blocked from general view on PERL in the interest of staff privacy.

11.24 Control of Antimicrobial Chemotherapy

Sensitivity testing

This is carried out using the Vitek 2 Compact and the EUCAST disc diffusion method. Tests are done on pure cultures of the isolated organism only.

Results of antimicrobial susceptibility testing are released after review by the consultant microbiologist.

11.25 Infection Control Service

The Hospital Infection Control Team provides advice and consultation on all aspects of infection control.

11.25.1 Hospital Infection Control Team

Infection Control Officer (Consultant Microbiologist)

Infection Control Nurse – Beep No. 8371

Nursing Administration Representative

Intensive Care Unit Sister

C.S.S.D Supervisor

Theatre Sister

Occupational Health Physician

Consultant Anaesthetist

Technical Services Manager

Pharmacist

Chief Executive

Staff Nurse Representative

11.25.2 Notifiable Infectious Diseases

Please notify all notifiable infectious diseases to: **Consultant Microbiologist and the Infection Control Nurse.**

The following diseases should be notified to:

East Counties Dublin, Kildare and Wicklow Medical Officer of Health, Department of Public Health, Room G29,

Dr Stevens' Hospital,

Dublin 8.

Phone: 01 6352145

Fax: 01 6352103of 2003)

Disease	**Causative Pathogen**
Acute anterior poliomyelitis	Polio virus
Ano-genital warts	Human papilloma virus
Anthrax	*Bacillus anthracis*
***Bacillus cereus* food-borne infection/intoxication**	*Bacillus cereus*
Bacterial meningitis (not otherwise specified)	
Botulism	*Clostridium botulinum*
Brucellosis	*Brucella* spp.
***Campylobacter* infection**	*Campylobacter* spp.
Carbapenem-resistant *Enterobacteriaceae* infection	Carbapenem-resistant *Enterobacteriaceae*
Chancroid	*Haemophilus ducreyi*
Chickenpox – hospitalised cases	Varicella-zoster virus

Disease	**Causative Pathogen**
Chikungunya disease	Chikungunya virus
***Chlamydia trachomatis* infection (genital)**	*Chlamydia trachomatis*
Cholera	*Vibrio cholerae*
Clostridioides *difficile*.infection	Clostridioides *difficile.*
***Clostridium perfringens* (type A) food-borne disease**	*Clostridium perfringens*
Creutzfeldt Jakob disease variant Creutzfeldt Jakob disease	
Cryptosporidiosis	*Cryptosporidium parvum, hominis*
Cytomegalovirus infection (congenital)	Cytomegalovirus
Dengue fever	Dengue virus
Diphtheria	*C. diphtheriae* or *ulcerans* (toxin producing)
Echinococcosis	*Echinococcus* spp.
Enterococcal bacteraemia	*Enterococcus* spp. (blood)
***Escherichia coli* infection (invasive)**	*Escherichia coli* (blood, CSF)
Giardiasis	*Giardia lamblia*
Gonorrhoea	*Neisseria gonorrhoeae*
Granuloma inguinale	*Klebsiella granulomatis*
***Haemophilus influenzae* disease (invasive)**	*Haemophilus influenzae* (blood, CSF/ sterile site)
Hepatitis A (acute) infection	Hepatitis A virus
Hepatitis B (acute and chronic) infection	Hepatitis B virus
Hepatitis C infection	Hepatitis C virus
Hepatitis E infection	Hepatitis E virus
Herpes simplex (genital)	Herpes simplex virus
Human immunodeficiency virus infection	Human immunodeficiency virus

Disease	Causative Pathogen
Human Monkeypox infection	Monkeypox virus of the orthopoxvirus genus
Influenza	Influenza A and B virus
***Klebsiella pneumoniae* infection (invasive)**	*Klebsiella pneumoniae* (blood or CSF)
Legionellosis	*Legionella* spp.
Leprosy	*Mycobacterium leprae*
Leptospirosis	*Leptospira* spp.
Listeriosis	*Listeria monocytogenes*
Lyme disease (neuroborreliosis)	*Borrelia burgdorferi*
Lymphogranuloma venereum	*Chlamydia trachomatis*
Malaria	*P. falciparum, vivax, knowlesi, ovale, malariae*
Measles	Measles virus
Meningococcal disease	*Neisseria meningitidis*
Monkey Pox	*Monkey Pox Virus*
Mumps	Mumps virus
Non-specific urethritis	
Noroviral infection	Norovirus
Paratyphoid	*Salmonella* Paratyphi
Pertussis	*Bordetella pertussis*
Plague	*Yersinia pestis*
***Pseudomonas aeruginosa* infection (invasive)**	*Pseudomonas aeruginosa* (blood or CSF)
Q Fever	*Coxiella burnetii*
Rabies	Rabies virus
Respiratory syncytial virus infection	Respiratory syncytial virus

Disease	**Causative Pathogen**
Rotavirus infection	Rotavirus
Rubella	Rubella virus
COVID-19	SARS-CoV-2
Salmonellosis	*Salmonella* spp. (not *S. Typhi* and *S. Paratyphi)*
Severe Acute Respiratory Syndrome (SARS)	SARS-associated coronavirus
Shigellosis	*Shigella* spp.
Smallpox	Variola virus
Staphylococcal food poisoning	Enterotoxigenic *Staphylococcus aureus*
***Staphylococcus aureus* bacteraemia**	*Staphylococcus aureus* (blood)
***Streptococcus* group A infection (invasive)**	*S.pyogenes* (blood, CSF, normally sterile site)
***Streptococcus* group B infection (invasive)**	*S. agalactiae* (blood, CSF, normally sterile site)
***Streptococcus pneumoniae* infection (invasive)**	*S.pneumoniae* (blood, CSF, normally sterile site)
Syphilis	*Treponema pallidum*
Tetanus	*Clostridium tetani*
Toxoplasmosis	*Toxoplasma gondii*
Trichinosis	*Trichinella* spp.
Trichomoniasis	*Trichomonas vaginalis*
Tuberculosis	*Mycobacterium tuberculosis* complex
Tularemia	*Francisella tularensis*
Typhoid	*Salmonella* Typhi
Typhus	*Rickettsia prowazekii*
Verotoxigenic *Escherichia coli* infection	Verotoxin producing *Escherichia coli*

Disease	Causative Pathogen
Viral encephalitis	
Viral haemorrhagic fevers	
Viral meningitis	
West Nile fever	West Nile virus
Yellow fever	Yellow fever virus
Yersiniosis	*Y. enterocolitica, Y.pseudotuberculosis*
Zika virus infection	Zika virus

11.25.3 Other Infectious Diseases

Other infections which are of importance as far as spread in hospital/patient welfare is concerned should be notified to: Dr. Margaret Hannan and the Infection Control Nurse; these are:

1. All methicillin (oxacillin) resistant staphylococcal infections.
2. All ESBL positive isolates
3. All positive Carbapenemase producing enterobacteriacae
4. All Vancomycin resistant enterococci
5. All positive Clostridioides Difficile A&B screens
6. Positive blood cultures.
7. Other exceptional resistant pathogens (e.g. VRSA / penicillin resistant GC)

The Infection Control Nurse has access to the following reports to monitor infection on PERL within the hospital:

- CSU report with growth.
- Any swabs/fluids/sputa, etc. with sensitivities.
- All MRSA screens whether positive or negative.
- Positive VRE/ CRE screens
- All reports with ESBL

- Environmental screens.
- Staff MRSA screens.

11.25.4 Reporting Of Suspected Outbreaks of Infection

When an outbreak of infection is suspected clinical staff must inform the infection Control Team immediately, to ensure prompt control and monitoring of the situation.

The Consultant Microbiologist may be contacted 'out of hours' via the Technician 'on call', if required.

An outbreak is declared when two or more associated cases of infection, or possible infection are detected and the Infection Control Nurse is informed immediately.

11.26 Test Library Codes

Test Code	Name
BAL	BAL Culture
BC	Blood Culture
CFR	COV-FLU-RSV Batch
CSF	CSF Culture
DEVICE	Device Culture
EPRP	Eplex Respiratory Panel
EYE	Eye Culture
FAPCR	Enteric PCR
FIT	Faecal Immunochemical Testing
FLUID	Fluid Culture
FMIC	Fluid Microscopy
FUN	Fungal Culture
GXCDIFF	Genxpert - C.diff
GXFLURSV	Genexpert: COV-FLU-RSV
GXNOR	Genexpert-Norovirus

Test Code	Name
HVS	HVS Culture
MDRO	Rectal Screen PCR
MOUTH	Mouth Culture
MRSA	MRSA Culture
PENILE	Penile Swab
Puss	Puss Culture
SPUTUM	Sputum Culture
STOOL	Stool Culture
THROAT	Throat Swab
TIP	Tipp Culture
TISSUE	Tissue Culture
UPREG	Pregnancy HcG
URINE	Urine Culture
VRECRE	Rectal Screen
WOUND	Wound Swab

Table 30: Codes for Microbiology Specimens

12. HISTOLOGY / CYTOLOGY

12.1 General Information

The department can be contacted at extension 8136.

The routine working hours of the Pathology Department of the Mater Private Hospital are;

Weekdays: 8am - 5pm

12.2 Reports & Turnaround Times

12.2.1 Histology Turn Around Times

The Histopathology National Quality Improvement (NQI) Programme divides Histopathology and Cytology specimens into categories according to the procedure (P) code within which turnaround times (TATs) are analysed. The NQAIS guidelines for reporting Histology cases on small specimens (PO4) aim to report 80% within 5 working days with the exception of P02 cases (GI Biopsies), these aim to be reported within 7 working days.

Large specimens (PO3) aim to be reported within the national QI (NQAIS) guidelines of 80% within 7 working days. Non-gynaecological cytology (PO6/PO&) is usually reported within two working days.

It is presently increasingly difficult for Histopathology Departments nationally, including the MPN Histopathology Department, to meet the NQAIS Target TAT guidelines for some routine cases. A process is in place to improve staffing and resources in the laboratory as we work towards achieving NQAIS Target TAT for all sample types. Our aim is to meet the NQAIS target TATs for all urgent cases (PO1).

At present, the Histopathology Laboratory in MPH will aim to report 80% of Histology cases within 15 working Days.

Add-On Special Stain	Additional 24 hours to 1 week
Add-On Immunocytochemistry	Additional 24 hours to 1 week
Add on Molecular testing	Additional 1 to 3 weeks

Frozen Section	Immediately (within 20 mins)
	Final report 24 hours – 1 week

NOTES:

Factors that may impact target TAT include the following: -

- Requirement to obtain additional clinical/radiological information
- Requirement for specimen decalcification
- Requirement to examine a large number of blocks/slides in a case
- Requirement for ancillary testing including levels, immunohistochemistry, special stains and external referral for molecular pathology.
- Requirement for Intradepartmental Consultation and multi-disciplinary review.

12.2.2 Cytology

Routine Cytology: Turn Around Time

Non-Gynaecology cytology cases (PO6/PO7) aim to be reported within 10 Working Days. Specimens from Theatre, Day therapy and X-Ray should be signed for in relevant specimen books held by those departments.

Cervical smears requests are packaged and dispatched to the Eurofins Biomnis for processing and reporting from the Histology Laboratory. The laboratory accepts and logs the cervical smears on the computer at specimen reception. They are dispatched to Eurofins (WI-HIST-0018 Procedure from sending out cervical smears to Biomnis). These cases are logged on the computer at the histology specimen reception

12.3 Medical Advice Outside Normal Working Hours

No out of hours service is provided. Urgent cases may be discussed with the Consultant staff when available. Out of hours frozen sections can **only** be performed by **prior arrangement** with the Consultant staff and Medical Scientist.

12.4 Consultant Advisory Service

Histopathology Consultants are available, either on site or in the MMUH. Consultant's rota and contact numbers available in tari-folder in Histology Department.

12.5 Histopathology Investigations

The department provides a service in surgical pathology and frozen section Histology. Specimens should be logged onto PERL and brought to the laboratory in sufficient 10% buffered formalin unless special investigations requiring fresh tissue are requested. Any fresh specimens must be brought to the attention of a Medical Scientist.
Specimens delivered to Histology must be accompanied with specimen logbook. Specimens will not be accepted into Histology without being logged into the logbook.

A Visual check is performed on acceptance of specimens in Histology department. If the information on the request form and the specimen do not match regarding the patient's name, DOB and/or MRN, the specimen will be rejected and returned to the source where it was taken.

Please Note: Histology specimens WILL NOT be signed for by other staff in the Pathology Department or during the on-call service.

Specimens cannot be left in the Histology Department without being signed in.

12.5.1 Urgent Specimens

A. Frozen Sections

A frozen section service is offered between 8.30am and 4.30 pm weekdays only. Frozen sections outside of these hours may be provided on an individual case basis **by prior agreement with the relevant Consultant Pathologist and Histology staff.** ***Please Note*** **that Frozen sections can ONLY be performed by prior arrangement with the Histology Laboratory and the Consultant Histopathologist. Frozen sections should be booked by the Consultant Surgeon 24 – 48 hours prior to the operation.**

NOTE: Specimens from patients with risk of infection (HepB, HepC, HIV, TB etc.) should not be submitted for frozen section. If a suspicion of such infection exists, the clinical staff concerned has a duty to inform laboratory personnel.

Procedure for Booking a Frozen Section

- Frozen Sections should be booked 24 - 48 hours in advance by contacting the Histology Laboratory on Ext. 8136 or at histology@materprivate.ie with details including Consultant Surgeon, patient name, type of specimen and time of surgery.
- If an emergency or un-booked (<24 hours) frozen section is required, the Consultant Surgeon involved should phone the Consultant Pathologist to discuss the requirement for frozen section and the ability of the laboratory to accommodate this request.
- The Theatre porter or Theatre staff on duty must bring the fresh specimen to laboratory. This sample must be logged on PERL prior to being brought to the laboratory. A contact phone number of clinician must be supplied with case to enable the pathologist to contact the consultant over the case.
- Under no circumstances should a specimen for frozen section be transported via the chute.
- Please inform the laboratory in the case of cancellation of frozen section.

Reporting of Frozen Sections

- The frozen section report will be phoned to the contact number provided. Failure to supply a contact number will result in a delay in the report being communicated to the clinician. A report will be available on PERL following routine paraffin processing of the specimen and the turnaround time of full diagnoses varies from specimen to specimen depending on the size and the complexity of the case.

B. Other URGENT Specimens

Urgent specimens are dealt with on an individual case basis following consultation with the Medical Scientists and/or Consultant Pathologist. The turnaround times of urgent cases varies according to the type of tissue to be processed, the optimum fixation time required and the complexity of the case.

All specimens ordered from Day Oncology, Emergency Department, Heart Centre Day Unit, X-ray and ITU are prioritised. Samples can also be ordered as urgent, but the laboratory should be contacted to ensure the sample is prioritised.

12.6 Specimens Requiring Special Handling

12.6.1 Muscle and Renal Biopsies

Muscle and Renal Biopsies should be brought to the laboratory immediately. They are dispatched via specimen reception to the Neuropathology and Renal Department Beaumont Hospital. They need to arrive at Beaumont Hospital no later than 4pm.

12.6.2 Lymph Nodes

Lymph nodes for suspected Lymphomas should be brought immediately to the Laboratory and brought to the attention of a Medical Scientist.

12.6.3 Breast Localization Biopsies

Wire guided breast biopsies are sent from Theatre to x-ray for imaging. They must be logged onto PERL then brought to Histology where laboratory staff will accept them.

12.6.4 Sural Nerve Biopsies/Peripheral Nerve Biopsies

Nerve Biopsies should be brought to the laboratory immediately. They are dispatched via specimen reception to the Neuropathology Department Beaumont Hospital.
They need to arrive at Beaumont Hospital no later than 4pm.

12.6.5 Specimens Requiring Both Microbiological Culture & Histology

Specimens requiring microbiological investigation e.g. Valves should be received fresh to the laboratory and always given to Microbiology first before any formalin is added.

12.6.6 Skin Biopsies for Immunofluorescence

Skin biopsies for Immunofluorescence should be brought to the laboratory immediately in soaked saline gauze. They are dispatched via specimen reception to the Immunology Department in the MMUH. They need to arrive at MMUH no later than 4:30pm.

Fresh specimens will not keep over the weekend. If delivering a Histology specimen personally to the laboratory each specimen must be handed to a Histology member of staff and signed into the specimen reception book as received.

12.7 Cytology Investigations

All cytology specimens should reach the laboratory before 4.00pm so that appropriate preparation can be performed.

12.7.1 Breast Cyst Aspirate

Place in Cytolyt solution.

12.7.2 Bronchial Aspirates

These should be sent to the Laboratory in a universal container prefilled with Cytolyt solution (available from the Laboratory).

12.7.3 Brushings from Other Sites

Place the brush in Cytolyt solution (available from the Laboratory) and send to the Laboratory.

12.7.4 Cerebrospinal Fluid

CSF needs preparing within two hours to avoid cell degeneration. Send in a sterile universal container. Cytology may only be performed if there is a white cell count of >5 (results from Microbiology).

12.7.5 Fine Needle Aspiration Cytology

Sites of aspiration include breast, thyroid and lymph nodes. The techniques require several passes of fine gauge needle through the organ with negative pressure on the syringe. Place the aspirate into Cytolyt solution (approximately 20-25mls is present within a universal container), the needle can then be washed out using the fluid. Transport to the laboratory immediately.

12.7.6 Sputum

Best results are achieved with freshly obtained sputa following chest physiotherapy, with an early morning sputum before the patient has eaten. Contamination with large amounts of saliva or food leads to inadequate specimens. Multiple specimens (usually x 3) may be necessary, but these should be sent on three separate days, not all taken at one time. Send in sterile sputum pots.

12.7.7 Urine

Best results are achieved with a fresh voided specimen, preferably not the first in the morning. Specimens at cystoscopy or catheterised patients should be labelled accordingly. No fixative is required but prompt transportation is recommended to avoid unnecessary repeat tests. Send in universal sterile container. It is not necessary to send multiple specimens.

12.7.7.1 How to take a Urine Specimen for Cytology

This is usually requested to screen for abnormal cells from the bladder.

1. This should not be taken the first-time urine is passed after waking in the morning. Any time after this is appropriate.
2. It is preferable to collect the urine at the end of the stream rather than the beginning.
3. Collect urine into the sterile container provided till half full.
4. Close container tightly and label the specimen.
5. Place in biohazard bag and seal.

12.7.8 Other Cytological Examinations

Examination of fluids and aspirates may be performed on request. Please contact the laboratory beforehand.

12.8 Notification of Critical Results to the Requester

Critical results including those from referral centres are telephoned by Pathologist, when appropriate, directly to the requesting clinician. Pathologists immediately notify clinicians when examination results for urgent samples/ frozen sections are available.

Critical Results include:

- Unexpected malignancy
- Fat in endometrial curetting's
- Fat in GI biopsy
- Life threatening infection
- Cardiac biopsies if rejection grade is >1R
- Acid fast bacilli
- Amended reports

Consultant Histopathologist will phone any critical results to the requesting Consultant.

13. POINT OF CARE TESTING

Point of care testing is testing performed near or at the site of the patient to provide timely test results that clinically and cost effectively contribute to immediate patient management decisions by a competent and trained healthcare professional. Please see **turnaround time** below in **Appendix No. 1: Alphabetical Repertoire of Tests.**

POCT available in the Mater Private under the remit of the Pathology Department are the following:

- Blood Gas Analysis
- Activated clotting times (ACT)
- Finger-prick Glucose
- Finger-prick Ketone
- Finger-prick Haemoglobin
- Urinalysis
- Urinary bHCG
- Finger-prick International Normalised Ratio (INR) test

It is the responsibility of the Head of Pathology, the relevant consultants and the POCT Co-ordinator to oversee point of care testing. The POCT Co-ordinator can be contacted in the biochemistry department on 8314 or by email POCT@materprivate.ie.

As with all diagnostic testing, POCT results may impact significantly on patient management and morbidity. Therefore, all samples (with the exception of finger pricks) **must be labelled** with the minimum requirement outlined in *3.8* above. Similarly, all patients must be identified and prepared as described above.

Responsibility and authorities, services agreement between internal and external users/suppliers in POCT processes should attend:

- **Training**: Users are fully trained and competent in accordance with the manufacturer's instructions for use. All initial training and super users training will be completed with a representative from by a representative from the company responsible for providing the POCT device. Super Users and POCT coordinator will replicate the training. Once training has been completed satisfactorily trainer and trainee must complete and sign the specific training form for each device. All Users of the POCT devices must complete the competency training form. By signing, the trainee acknowledges understanding of the training, and the trainer acknowledges demonstrated competency in the procedures. Training form is maintained by the Point of Care Coordinator.
- **Procedures**: Users are familiar with and have read the relevant standard operating procedures and working instructions related to the specific point of care test (i.e. *CM-POCT-0001*) all point of care documentation can be found on QPulse using the keyword POCT.
- **Equipment**: The POCT coordinator is responsible for all POCT analysers. It is the responsibility of all users to ensure that adequate use and maintenance are in place and a safe working condition and working order is maintained, according to the manufacturer's instructions and SOP`s and are never used when inadequate conditions, as internal control outside the range, performance error or malfunction.
- **Consumables:** The POCT coordinator is responsible for equipment, reagents and consumables pertaining to all POCT analysers. It is the responsibility of all users to ensure that there are adequate stocks of reagents, and that reagents and consumables are stored according to the manufacturer's instructions and are never used past their expiry date.
- **Maintenance:** Users are familiar with individual SOPs and user's manuals (where appropriate) for more detailed descriptions of how and when to perform maintenance. All equipment maintenance is controlled by POCT Team using *CF-POCT-0050 Preventive Maintenance Schedule POCT* and *CF-POCT-0079 POCT Assets Electrical*

Check Control with all data information about PM and Electrical Checks, as well as Supplier Contacts. Contracts and SLAs from supplies can be found on QPulse and POCT drive.

- **Reporting Results / Clinical Interpretation:** Users are familiar that results are reported in accordance with clinical protocol and that they are aware of the critical limits for each POCT test and report as per *POL-GEN-032 Verbal and Telephone Orders/ Critical Results Policy*. Critical limits can be found in the relevant working instruction WI-POCT-0013 and /or *CM-POCT-0001*. Clinically interpreting results derived from a POCT device is the responsibility of the trained individual who performs the test.
- **IQC:** Users are familiar that is required participating in internal quality control (IQC) periodically following instructions from operational procedures.
- **EQA:** External quality assurance (EQA) testing when required should be processed accordingly if instructions for each POCT scheme.
- **Quality Management:** POCT Quality Objectives, Quality Indicators, Internal Audits are periodically planned, defined and performed by POCT team, heads of the departments and lab manager, and presented on POCT steering group committee, where are evaluated, reviewed, required corrective or preventive action and recorded on QPulse and POCT drive.
- **Risk Assessment:** Users are familiar about individual test SOP with details of risk assessment and SDS. Refer to *RA-HS-0015 Risk Assessment Laboratory.*
- **Contracts and SLAs** from supplies can be found on QPulse and POCT drive. For service agreements with users that use POCT services, clinical staff contact, and manufacturer contact can be found on *CF-POCT-0078 POCT Assets Inventory Overview.* It is the responsibility of all users to ensure that adequate use and maintenance are in place and a safe working condition and working order is maintained, according to the manufacturer's instructions.
- **Communications and alignment** for POCT management and performance, responsibilities and services are processed by POCT Steering Group Committee. The

function of the POCT committee is to provide a channel for communication between the POCT coordinator, the clinical staff and the laboratory manager. Records are kept on QPulse.

Please refer to *CM- POCT-0001 Management of Point of Care Testing* for the full point of care policy.

14. SUPPORTING DOCUMENTATION

Ref.: PLA-QUA-001 Mater Private Group Quality and Patient Safety Plan 2024 Patient

Ref.: PLA-GEN-113 OPEN DISCLOSURE POLICY Ⓝ

15. APPENDICES

Appendix No. 1: Alphabetical Repertoire of Tests

Appendix No. 1: Alphabetical Repertoire of Tests

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
Activated Partial Thromboplastin Time	Na Citrate 9NC 3 ml	Fill to line indicated on bottle. For patients on heparin. APTT needs to be measured within 2 hours of phlebotomy	2 Hours	25.1-32.9 seconds	Haematology
Activated Clotting Times (ACT)	Arterial or venous blood is drawn into a 2ml syringe	Freshly drawn blood to be processed at the bedside immediately	5 minutes	Contact the cardiac registrar/anaesthesiologist for the interpretation and management of results.	Point of Care
Alanine Aminotransferase	Serum-Gel 7.5ml	Analyse as soon as possible or spin/separate	2.5hrs or 70 Minutes STAT	M <41 IU/L F <33 IU/L	Biochemistry
Albumin	Serum-Gel 7.5ml	Analyse as soon as possible or spin/separate	2.5hrs or 70 Minutes STAT	<14yr 38-54 g/L 14-18yr 32-45 g/L >18yr 35-52 g/L	Biochemistry
Alkaline Phosphatase	Serum-Gel 7.5ml	Analyse as soon as possible or spin/separate	2.5hrs or 70 Minutes STAT	<10yr 142-335 IU/L 10-<13yr 129-417 IU/L	Biochemistry

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
				13-15yr M 116-468 IU/L 13-15yr F 57-254 IU/L 15-17 M 82-331 IU/L 15-17 F 50-117 IU/L 17-19 M 55-149 IU/L 17-19 F 45-87 IU/L >19 M 40-129 IU/L >19 F 35-104 IU/L	
Amylase	Serum-Gel 7.5ml	Analyse as soon as possible or spin/separate	2.5hrs or 70 Minutes STAT	28-100 IU/L	Biochemistry
*Anti LKM Antibody	7.5 ml clotted	Spin, separate and store at 2-8^{o}C	1 Week	<80	Immunology
*Anti Mitochondrial Antibody	7.5 ml clotted	Spin, separate and store at 2-8^{o}C	1 Week	<80	Immunology
*Anti-Nuclear Antibody (Anti-Nuclear Factor)	7.5ml clotted	Spin, separate and store at 2-8^{o}C	1Week	<80	Immunology

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
*Anti-Nuclear Antibody Patterns (Hep 2 Pat)	7.5 ml clotted	Spin, separate and store at 2-8^{o}C	1 Week	N/A	Immunology
*Anti Smooth Muscle Antibody	7.5ml clotted	Spin, separate and store at 2-8^{o}C	1 Week	<80	Immunology
*Antibody Screen Auto Antibody Screen	7.5 ml clotted	Spin, separate and store at 2-8^{o}C	1 Week	<80	Immunology
*Anti-HBc	7.5 ml clotted	Spin and store at 2-8^{o}C	3 Days	Positive/Not detected	Serology
*AntiHBs	7.5 ml clotted	Spin and store at 2-8^{o}C	3 Days	Positive/Not detected	Serology
Arterial Blood Gas	ABG Heparin Syringe	Ensure there are no air bubbles and analyse immediately. Use Lithium Hep. Syringe	30 Minutes	PH: 7.35 -7.45 kPa PCO2: 4.5-6.0 kPa PO2: 11.0-14.5 kPa Std. Bicarb: 22.4-25.8mmol/L O2 Sat: 95-98% Base Excess -2.3-+2.3 mmol/L	Point of Care
Aspartate Aminotransferase	Serum-Gel 7.5ml	Analyse as soon as possible or spin/separate	2.5hrs or 70 Minutes STAT	M <40 IU/L F <32 IU/L	Biochemistry

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
*B12	7.5ml Serum		1 Day	197 – 771 pg/mL	Biochemistry
*Bence Jones Protein	24 hr urine collection (Plain Container)	Urines should be fresh for analysis and stored at 2-8^{o}C. A 24-hour collection is preferable. An early morning urine specimen may be analysed. However, if Bence Jones protein is present it cannot be quantified.	1 Week	Positive/Negative	Immunology
*Beta-2 Microglobulin	7.5ml clotted	Spin, and store at 2-8^{o}C	1 week	0.8-2.34 mg/L	Immunology
BHCG /Human Chorionic Gonadotropin Beta	Serum-Gel 7.5mls	Analyse as soon as possible or spin/separate	Daily or 90 mins STAT	<5 IU/L Can be up to 9 in menopausal woman due to pituitary secretion	Biochemistry
BHCG /Human Chorionic Gonadotropin Beta (POCT)	Spot Urine	Performed in Siemens Clinitek Status +	4 minutes	>25 IU/ml = positive >10<25 IU/ml = borderline <10 IU/ml – negative	Point of Care
Bicarbonate	Serum-Gel 7.5ml	Send to the laboratory promptly.	2.5hrs or 70	22-29 mmol/L	Biochemistry

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
			Minutes STAT		
Blood Culture	Blood	N/A	Neg: 2 Days Pos: 7 Days	N/A	Microbiology
Blood Film Review	Blood Film		2 Working Days	N/A	Haematology
*Ca125	Serum-Gel 7.5ml	Analyse as soon as possible	1 Day Weekday	0-35U/ml	Biochemistry
*Ca153	Serum-Gel 7.5ml	Analyse as soon as possible	1 Day Weekday	<26.4 U/ml	Biochemistry
Calcium	Serum-Gel 7.5ml	Analyse as soon as possible or spin/separate	2.5hrs or 70 Minutes STAT	2-12yr 2.20-2.70 mmol/L 12-18 yr 2.10 – 2.55 mmol/L 18-60yr 2.15-2.50 mmol/L 60-90yr 2.20-2.55 mmol/L >90yr 2.05-2.40 mmol/L	Biochemistry
Calcium-Adjusted	Calculation	Calculation Based on Albumin and calcium	2.5hrs or 70 Minutes STAT	Not calculated for Alb <20 Reference range same as Calcium	Biochemistry

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
*CEA	Serum-Gel 7.5ml	Analyse as soon as possible	1 Day Weekday	0.0-5.2 µg/l	Biochemistry
Chloride	Serum-Gel 7.5ml	Analyse as soon as possible	2.5hrs or 70 Minutes STAT	95-108 mmol/L	Biochemistry
Cholesterol	Serum-Gel 7.5ml	12 hour fast. Analyse as soon as possible or spin/separate	2.5hrs or 70 Minutes STAT	<5.2 mmol/L optimal	Biochemistry
*Correction Studies	Na Citrate 9NC 3 ml		½ Day	Reduction of Original Results (secs)	Haematology
*Cortisol	Serum-Gel 7.5ml	Analyse as soon as possible or spin/separate	2.5hrs or 90mins STAT	133-537 nmol/L for morning samples (6-10am)	Biochemistry
COVID-19/FLU/RSV	NP/OP in UTM	Urgent samples should be hand deliver to Laboratory ASAP	4hrs	N/A	Microbiology
*CRE Screen	Rectal swab/ Stool	Blue top amies swab	Neg: 2 Days Pos: 4 Days	N/A	Microbiology
C-Reactive Protein	Serum-Gel 7.5ml	Analyse as soon as possible or spin/separate	2.5hrs or 70 Minutes STAT	0-5.0 mg/L	Biochemistry

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
Creatine Kinase	Serum-Gel 7.5ml	Analyse as soon as possible or spin/separate. Samples must be centrifuged within 2hrs of venepuncture.	2.5hrs or 70 Minutes STAT	M=39-308 IU/L F=26-192 IU/L	Biochemistry
Creatinine	Serum-Gel 7.5ml	Analyse as soon as possible or spin/separate. Sample must be received in laboratory within 2 hrs of venepuncture.	2.5hrs or 70 Minutes STAT	5-7yr 25-42 µmol/L 7-9yr 30-47 µmol/L 9-11yr 29-56 µmol/L 11-13yr 39-60 µmol/L 13-15yr 40-68 µmol/L F : 45-84 µmol/L M: 59-104 µmol/L	Biochemistry
*Cryoglobulin	2 x 7.5ML clotted 1 x 2.7ml EDTA	Contact phlebotomist regarding special requirements	1 Week	Positive/Negative	Immunology
*CSF Microscopy, C&S	CSF	Must be received within 1 hour for glucose analysis.	Neg: 3 Days Pos: 4 Days	N/A	Microbiology

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
*CSF Protein & Glucose	1.0ml CSF	Send to Laboratory immediately.	70 Minutes	15-45 mg/dL 2.22-3.89 mmol/L	Biochemistry
D Dimers	Na Citrate 9NC 3ml		2 Hours	<0.50ug/ml	Haematology
*Deep Wound / Tissue	Tissue	N/A	Neg: 2 Days Pos: 14 Days	N/A	Microbiology
*Differential	K EDTA 2.7 ml		Same Day	<u>NEUT</u> 6 years 2.00-6.00 x $10^{9/}$L Adult 2.00-7.50 x $10^{9/}$L <u>LYMP</u> 6 years 5.50-8.50 x $10^{9/}$L Adult 1.50-4.00 x $10^{9/}$L <u>MONO</u> 6 years 0.70-1.50 x $10^{9/}$L Adult 0.20-0.80 x $10^{9/}$L <u>EOSI</u> 6 years 0.30-0.80 x $10^{9/}$L	Haematology

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
				Adult 0.04-0.40 x 10^{9}/L BASO 0.00-0.10 x 10^{9}L	
Digoxin	Clotted 7.5ml (plain)	Analyse as soon as possible or spin/separate	2.5hrs or 70 Minutes STAT	0.77-1.5 nmol/L	Biochemistry
eGFR	Calculation	Based on the 2009 EPI formula		<120mls/min	Biochemistry
Erythrocyte Sedimentation Rate	Na Citrate 4NC 3.5 ml		2 Hours	0-10 Male 0-20 Female	Haematology
*Eye / Ear / Nose / Throat	Swab/ pus	Blue top amies swab	Neg: 2 Days Pos: 4 Days	N/A	Microbiology
*Faecal C. difficle	Faeces	N/A	2 Days	N/A	Microbiology
*Faecal Immunochemical Test (FIT)	Faeces/ Inoculated Collection Tube	N/A	2 Days	N/A	Microbiology
*Faecal M, C&S	Faeces	N/A	Neg: 4 Days Pos: 5 days	N/A	Microbiology

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
*Ferritin	7.5ml Serum		1 Day	(m) 30 – 400ug/L (f) 13 – 150 ug/L	Biochemistry
Fibrinogen	Na Citrate 9NC 3 ml		2 Hours	2.0-4.0 g/l.	Haematology
*Folate	7.5ml Serum		1 Day	3.9 – 26.8 ng/L	Biochemistry
Full Blood Count	K EDTA 2.7 ml	Haemoglobin: it is important to avoid haemolysis either during or after the collection of the blood specimen, otherwise the result is invalid. Red cell count: there is a moderate fluctuation during the 24 hours of about 4 per cent probably related to exercise meals and fluid intake etc. Strong emotions such as fear cause a temporary increase in the red cell count. Platelets: pseudo thrombocytopenia	1 Hour	<u>WBC</u> 12 years 4.5-13.5 x $10^{9/}$L Adult 4.00-11.00 x $10^{9/}$L <u>RBC</u> 12 years 4.00-5.40 x $10^{12/}$L Adult (f)3.80-5.80 x $10^{12/}$L Adult (m)4.50-6.50 x $10^{12/}$L <u>HGB</u> 12 years 11.5-14.5 g/dL Adult (f) 11.5-16.5 g/dL Adult (m) 13.0-18.0 g/dL <u>HCT</u>	Haematology

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
		due to platelet aggregation (clumping) in EDTA blood may be found. This artefact is of no clinical significance, can be identified in the laboratory and resolved by supplying Thromboexact specimen for platelet count only. While red cell white cell and platelet numbers are stable for at least 24hours in EDTA, progressive morphological changes in a blood film are however inevitable		12 years 0.37-0.44 x L/L Adult (f) 0.37-0.47 x L/L Adult (m) 0.40-0.54 x L/L MCV 12 years 77.0-91.0 f/L Adult 80.0-100.0 f/L MCH 12 years 24.0-30.0pg Adult 28.0-32.0pg MCHC 32.0-36.0 g/dL RDW 11.0-15.0% PLTS 150-400 x $10^{9/}$L	
Gamma Glutamyl Transferase	Serum-Gel 7.5ml	Analyse as soon as possible or Spin/separate	2.5hrs or 70 Minutes STAT	M: 10-71 U/L F: 6-42 U/L	Biochemistry
*Genital Swab	Swab	Blue top amies swab	Neg: 2 Days Pos: 4 Days	N/A	Microbiology
Gentamicin	Clotted 7.5ml	Analyse as soon as possible or	2.5hrs or 70	Refer to Consultant	Biochemistry

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
	(Plain)	spin/separate	Minutes STAT	Microbiologist	
Glucose	Finger prick sample, Nova StatStrip meter	N/A	1 minute	3.9-5.6 mmol/L	Point of Care
Glucose	Fluoride Oxalate Bottle 2.5ml	12 hours fast. Analyse as soon as possible. Serum sample must be received within one hour of venepuncture. Fluoride Oxalate tubes should be used	2.5hrs or 70 Minutes STAT	3.9-5.6 mmol/L	Biochemistry
Glucose Tolerance Test	2 x 2.5ml bottles Fluoride Oxalate Bottle	See instructions for modified GTT testing.	2.5hrs or 70 Minutes STAT	Fasting <5.6 mmol/L 2hrs pp <7.8 mmol/L	Biochemistry
*Haemoglobin HBA1C	Whole Blood (EDTA) 2.5mls	Use EDTA Sample	1 Day (Weekday)	20-42 mmol/mol	Biochemistry
Haemoglobin	Finger prick sample	N/A	1 minute	Hb (Male) - 13-17 g/dl[2] Hb (Female) - 12-15 g/dl[2]	Point of Care

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
*Hepatitis A	7.5 ml clotted	Spin and store at 2-8°C	3 Days	Positive/Not detected	Serology
*Hepatitis B (HBsAg)	7.5 ml clotted	Spin and store at 2-8°C	3 Days	Positive/Not detected	Serology
*Hepatitis C	7.5 ml clotted	Spin and store at 2-8°C	3 Days	Positive/Not detected	Serology
High Density Lipoprotein	Serum-Gel 7.5mls	12 hours fast	2.5hrs	>1.0 mmol/L	Biochemistry
*HIV	7.5 ml clotted	Spin and store at 2-8°C	3 Days	Positive/Not detected	Serology
Hs-Troponin T	Serum-Gel 7.5ml	Analyse as soon as possible or spin/separate	75 Minutes	0-14 ng/L Female 0-22 ng/L Male Values > 300 ng/L indicates a significant degree of myocardial damage, which may be consistent with MI. Values 22-300 ng/L In patients with symptoms of ACS requires Clinical Correlation.	Biochemistry
*HVS – High Vaginal Swab	Swab	Blue Top Amies Swab	Neg: 2 Days	N/A	Microbiology

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
			Pos: 4 days		
*Immunofixation of serum.	7.5 ml clotted	Spin, separate and store at 2-8°C	2 Weeks	Interpretative comment	Immunology
*Immunofixation of urine	24 hr urine collection (Plain Container)	As Above	2 Weeks	Interpretative Comment	Immunology
*Immunoglobulins	7.5ml clotted	Spin and store at 2-8°C	1 Week	IgG 6.0-16.0g/L IgA 0.85-4.99 g/L IgM 0.35-2.42g/L	Immunology
Influenza / RSV	NP Swab in UTM	Hand deliver to Laboratory ASAP	2hrs (Genexpert)	N/A	Microbiology
Inorganic Phosphate	Serum-Gel 7.5ml	Analyse as soon as possible or spin/separate	2.5hrs or 70 Minutes STAT	4-6yr 1.05-1.80 mmol/L M:7-9yr 0.95-1.75mmol/L F:7-9yr 1.00-1.80 mmol/L	Biochemistry

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
				M:10-12yr 1.05-1.85 mmol/L F:10-12yr 1.05-1.70 mmol/L M:13-15yr 0.95-1.65 mmol/L F:13-15yr 0.90-1.55 mmol/L M:16-18yr 0.85-1.60 mmol/L F:16-18 0.80-1.55 mmol/L Adult 0.81-1.45 mmol/L	
International Normalised Ratio	Na Citrate 9NC 3 ml		2 Hours	Determined by clinical state	Haematology
International Normalised ratio	Finger Prick	8µL (the blood drop must be a minimum of 8µL in volume. Low sample volume will cause an error message.)	1 minute	2.0 – 3.5 mmol/L	Point of Care
Iron	Serum-Gel 7.5ml	Analyse as soon as possible or spin/separate. Sample must be received in laboratory within one hour of venepuncture.	2.5hrs or 80 Minutes STAT	5.83-34.5 µmol/L	Biochemistry

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
*Iron Stain	Bone Marrow Aspirate Slide		2 Days	Reduced/Normal/Raised	Haematology
*Joint Fluid	Fluids	N/A	14 Days	N/A	Microbiology
Ketones	Finger prick, Nova StatStrip meter	N/A	1 minute	0-0.6 mmol/l	Point of Care
Lactate	ABG Heparin Syringe (venous/ arterial sample)	Analyse as soon as possible or spin/ separate. Must be received in lab within 2hrs of venepuncture.	30 Minutes	0.5-2.0mmol/l	Point of Care
Lactate Dehydrogenase	Serum-Gel 7.5ml	Ensure there are no air bubbles and analyse immediately.	2.5hrs or 70 Minutes STAT	2-15yr 120-300 IU/L F: 135-214 IU/L M: 135-225 IU/L	Biochemistry
Low Density Lipoprotein	Serum-Gel Cl 7.5mls	Analyse as soon as possible or spin/separate	2.5hrs	<3.0 mmol/L optimal	Biochemistry
*LPa	Serum-Gel 7.5ml	thawing /freezing only once	Weekly	<75 nmol/L	Biochemistry
Magnesium	Serum-Gel 7.5ml	Analyse as soon as possible or	2.5hrs or 70	6-12yr 0.70-0.86 mmol/L	Biochemistry

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
		spin/separate	Minutes STAT	12-20yr 0.70-0.91 mmol/L 20-60yr 0.66-1.07 mmol/L 60-90yr 0.66-0.99 mmol/L >90yr 0.70-0.95 mmol/L	
*May Grunwald /Giemsa	Bone Marrow Aspirate Blood Film		2 Days Same Day	N/A	Haematology
*MRSA	Nose/Throat/ Groin swabs	N/A	Neg: 2 Days Pos: 3 Days	N/A	Microbiology
Non-HDL	Calculation	Based on total chol, HDL chol and LDL chol.	2.5hrs or 70 Minutes STAT	<3.4 mmol/L optimal	Biochemistry
NT-pro-BNP	Serum-Gel 7.5mls	Analyse as soon as possible	90 mins	<125 pg/ml	Biochemistry
*Parietal Cell Antibody	7.5ml clotted	Spin, separate and store at 2-8^{o}C	1 Week	<80	Immunology
*Peri-Cardial Fluid	Fluid	N/A	Neg: 3 Days Pos: 7 Days	N/A	Microbiology

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
Potassium	Serum-Gel 7.5ml	Send to laboratory within 2 hrs of venepuncture	2.5hrs or 70 Minutes STAT	3.5-5.3 mmol/L	Biochemistry
Pregnancy Test	Urine	N/A	30 Mins	N/A	Microbiology
*Prostate Specific Antigen	Serum-Gel 7.5mls	Analyse as soon as possible or spin/separate	Batched every 2hrs. ~3hrs	0-2.9 ug/L <50 yrs 0-2.9 ug/L 50-59 yrs 0-3.9 ug/L 60-69 yrs 0-5 ug/L >70yrs	Biochemistry
*Protein Electrophoresis Quantitative Paraprotein	7.5 ml clotted	Spin, separate and store at 2-8^{o}C	1 Week	Total Protein 64-82 g/L Albumin 35-50 g/L Alpha-1 1-2 g/L Alpha-2 6-9 g/L Beta-1 4-7 g/L Beta-2 2-5 g/L Gammaglobulin 6-13 g/L Interpretative comment	Immunology
*Protein/Creatinine Ratio	MSU	UK eCKD guidelines	24 Hours	1-15 mg/mmol	Biochemistry

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
			(weekdays)		
Prothrombin Time	Na Citrate 9NC 3 ml556f6ff		2 Hours	11.4-15.0 seconds	Haematology
Progesterone	7.5ml clotted		Weekdays	Follicular: 0.2-0.6 nmol/L Mid Cycle: 0.2-13 nmol/l Luteal: 13-46 nmol/l Post Menopause: 0.2-0.6 nmol/l	Biochemistry
*PTH	Whole Blood (EDTA) 2.5mls	Analyse as soon as possible or spin/separate	Daily or 90 mins STAT	1.6-6.9 pmol/L	Biochemistry
*Reticulocytes	K EDTA 2.7 ml		Same Day	35-132x$10^{9/}$L	Haematology
*Serum Free Light Chains	7.5ml clotted	Spin, and store at 2-8^{o}C	14 days	Kappa: 3.3-19.40 mg/L Lambda: 5.71-26.30 mg/L K/L Ratio: 0.26-1.65	Immunology
SHBG	7.5ml clotted		WEEKDAYS	Male:20-49yr 18.3-54.1nmol/l Male:>50yr 20.6-76.7	Biochemistry

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
				Female:20-49yr 32.4-128nmol/l Female: >50yr 27.1-128nmol/l	
*Sickledex	K EDTA 2.7 ml		Same Day	Positive/Negative	Haematology
Sodium	Serum-Gel Clotted 7.5ml	Analyse as soon as possible. Sample should be received in laboratory within 1 hour of venepuncture.	2.5hrs or 70 Minutes STAT	133-146 mmol/L	Biochemistry
*Sputum / BAL / Other Resp Samples	Sputum	N/A	Neg: 2 Days Pos: 5 Days	N/A	Microbiology
*Superficial Wound / Pus	Swab/ pus	Blue top amies swab	Neg: 3 Days Pos: 14 Days	N/A	Microbiology
*Syphillis	7.5 ml clotted	Spin and store at 2-8^{o}C	3 Days	Positive/Not detected	Serology
Testosterone	7.5 ml clotted		Weekdays	Male: 20-49yr 8.6-29nmol/l Male: >50yr 6.7-25.7nmol/l Female: 20-49yr 0.3-1.7nmol/l Female:>50yr0.1-1.42nmol/	Biochemistry
*Thyroid Simulating	Serum-Gel 7.5ml	Analyse as soon as possible	Daily or 90mins	0.270-4.45 mIU/L	Biochemistry

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
Hormone			STAT		
*Thyroxine Free	Serum-Gel 7.5ml	Analyse as soon as possible	Daily or 90 mins STAT	12-22 pmol/L	Biochemistry
*Tips Culture	Tips and lines and pacing wires	Only processed if blood cultures received within 24 hours	3 Days	N/A	Microbiology
Total Bilirubin	Serum-Gel 7.5ml	Analyse as soon as possible or spin/separate	2.5hrs or 70 Minutes STAT	M <24 µmol/L F <15 µmol/L	Biochemistry
Total Protein	Serum-Gel 7.5ml	Analyse as soon as possible or spin/separate	2.5hrs or 70 Minutes STAT	60-80 g/L	Biochemistry
Transferrin	Serum-Gel 7.5ml	Analyse as soon as possible or spin/separate	2.5hrs	2.0-3.6 g/L	Biochemistry
Transferrin saturation	Calculation		2.5hrs	16-45%	Biochemistry
Triglycerides	Serum-Gel 7.5ml	Analyse as soon as possible or spin/separate	2.5hrs	<1.7 mmol/L	Biochemistry
Urate	Serum-Gel 7.5ml	Analyse as soon as possible or	2.5hrs or 80	M: 202-417 µmol/L	Biochemistry

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
		spin/separate	Minutes STAT	F: 142-339 µmol/L	
Urea	Serum Gel 7.5ml	12 hours fast. Analyse as soon as possible or spin/separate	2.5hrs or 70 Minutes STAT	18-60yr 2.14-7.14 mmol/L 60-90yr 2.86-8.21 mmol/L	Biochemistry
*Urinary Amylase	MSU Container	Analyse as soon as possible	2 hours	M: 16-491 U/L F: 21-447 U/L	Biochemistry
*Urinary Calcium	24hr plain Container/MSU	Analyse as soon as possible	24 Hours (weekdays)	2.5-7.5 mmol/24hr	Biochemistry
*Urinary Calcium/creatinine ratio	Calculation		24 Hours (weekdays)	0.3-0.7 mmol/mmol	Biochemistry
*Urinary Creatinine Creatinine Clearance	24hr container/MSU container	Analyse as soon as possible	24 Hours (weekdays)	M: 3540-24600 µmol/L F: 2550- 66-143 ml/min	Biochemistry
*Urinary Potassium	24 hr urine /MSU container		24 Hours (weekdays)	Interpret in conjunction with Serum K and water intake	Biochemistry

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
*Urinary Protein	24 hr urine container	Analyse as soon as possible	24 Hours (weekdays)	<0.14 g/24 Hours	Biochemistry
Urinary Protein/creatinine ratio	24 hr urine /MSU container		24 Hours (weekdays)	1-15mg/mmol	Biochemistry
Urinary Sodium	24 hr urine /MSU container		24 Hours (weekdays)	Interpret in conjunction with Serum Na and water intake	Biochemistry
*Urinary Urea	24hr Plain Urine container	Analyse as soon as possible	24 Hours (weekdays)	428-741 mmol/24hrs	Biochemistry
*Urine Microscopy, C&S	Urine	N/A	Neg: 1 Day Pos: 3 Days	N/A	Microbiology
Urinalysis	Urine	Urine must be collected in a clean dry container	4 minutes	Results should be interpreted in conjunction with the patient's medical history and clinical details and full details of Expected values, Performance Characteristics, Sensitivity	Point of Care

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
				Values and Test Limitations can be found in the product insert (EX-POCT-0008Multistix Package Insert).	
Vancomycin	Clotted 7.5ml Sample to be taken 5 minutes pre-dose and 1 hour post dose	Analyse as soon as possible or spin/separate	2.5hrs or 80 Minutes STAT	Refer to Consultant Microbiologist	Biochemistry
Vitamin D	Clotted		Daily(weekdays)	>50nmol/L	Biochemistry
Venous (VBG) Blood Gas	VBG Heparin Syringe	Ensure there are no air bubbles and analyse immediately. Use Lithium Hep. Syringe	30 Minutes	PH: 7.35-7.45 kPa PCO2: 8.0-11.0 kPa PO2: 6.0-8.0 kPa Std. Bicarb: 22.4-25.8 mmol/L O2 Sat: 85-90% Base Excess: N/A	Point of Care

Test *Tests are not performed on call	**Sample Type**	**Special Precautions**	**Turn Around Time**	**Adult Reference Ranges**	**Department**
*VRE Screen	Rectal swab/ Stool	Blue top amies swab	Neg: 3 Days Pos: 4 Days	N/A	Microbiology